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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, 455, and 460

[CMS-4190-F2]

RIN 0938-AT97

Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare Cost Plan program, and Programs of All-Inclusive Care for the Elderly (PACE) to implement certain sections of the Bipartisan Budget Act of 2018 and the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment- (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act), enhance the Part C and D programs and the PACE program, codify several existing CMS policies, make required statutory changes, implement other technical changes, and make routine updates. As stated in the final rule that appeared in the **Federal Register** on June 2, 2020, CMS is fulfilling its intention to address the remaining proposals from the February 2020 proposed rule here. Although the provisions adopted in this second final rule will be in effect during 2021, most provisions will apply to coverage beginning January 1, 2022.

Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that were already in effect prior to this rule's appearance in the **Federal Register**, CMS reminds organizations, plan sponsors, and other readers that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the SUPPORT Act, CMS intends to implement these statutory provisions consistent with their effective provisions.

DATES: Effective Date: These regulations are effective [Insert **60 days after the date of publication in the Federal Register]**.

Applicability Dates: Most of the provisions in this rule will be applicable to coverage beginning January 1, 2022, except as noted below.

The Part D Income Related Monthly Adjustment Amount (IRMAA) calculation update in § 423.286(d)(4)(ii) is applicable [Insert **60 days after the date of publication in the Federal Registe**r]. The provision defining targeted beneficiaries for MTM at § 423.153(d)(2) is applicable [Insert **60 days after the date of publication in the Federal Register]**. The provisions on automatic escalation to the independent outside entity under a Medicare Part D drug management program (DMP) at §§ 423.590(i) and 423.600(b) and the related provisions on information on appeal rights in the beneficiary notices at §§ 423.153(f)(5)(ii)(C)(*3*), 423.153(f)(6)(ii)(C)(*4*), and 423.153(f)(8)(i) are applicable [Insert **60 days after the date of publication in the Federal Registe**r]. The provisions defining the term "parent organization" for MA and Part D plans at §§ 422.2 and 423.4 are applicable [Insert **60 days after the date of publication in the Federal Register].** The General Requirements for Applicable Integrated Plans and Continuation of Benefits provisions at §§ 422.629 and 422.632 are applicable [Insert **60 days after the date of publication in the Federal Register].**

In order to help ensure that Part D sponsors have sufficient implementation time, the beneficiary real time benefit tool (RTBT) (§ 423.128(d)(4)) requirement will not be applicable

until January 1, 2023.

Due to operational considerations, revisions to the Special Needs Plan Model of Care requirements in § 422.101(f) are intended for implementation (that is, applicability) for models of care for contract year 2023. Plans that are required to submit models of care for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for full implementation and enforcement of the final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

SUPPLEMENTARY INFORMATION: The Code of Federal Regulations (CFR) will be updated consistent with the respective effective date of each provision. The applicability and effective dates are discussed in the summary and preamble for each of these items. Because CMS is finalizing the call center, marketing, and communications requirements under §§ 422.111(h)(1), 422.2260 through 422.2274, §§ 423.128(d)(1), and 423.2260 through 423.2274 as applicable for the contract year and coverage beginning January 1, 2022, these requirements will apply to call center operations, marketing, and mandatory disclosures occurring in 2021 for enrollments made for contract year 2022.

FOR FURTHER INFORMATION, CONTACT:

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs:

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018), and
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act).

The rule also includes a number of changes to: strengthen and improve the Part C and D programs and the PACE program, codify in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other guidance documents, make required statutory changes, implement other technical changes, and make routine updates.

In the June 2020 final rule (85 FR 33796), CMS addressed a selection of proposals from the February 2020 proposed rule (85 FR 9002). In this final rule, CMS is addressing the remaining proposals from the February 2020 proposed rule with two exceptions: 1) Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101) and 2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). Therefore, we may address the two remaining proposals from the February 18, 2020, proposed rule (85 FR 9002) not included in this final rule in subsequent rulemaking.

In so doing, the final rule addresses the following needs for federal regulatory action as set forth below:

- The regulations implementing the provisions of BBA of 2018 relating to Medicare Advantage Special Needs Plans address, as directed by law, care management requirements through the development and implementation of models of care., Given the context of these provisions is a federal program, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions implementing the provisions of BBA of 2018 relating to the Coverage Gap Discount Program and the Part D Income Related Monthly Adjustment Amount (IRMAA) improve the operation of government programs by ensuring the regulations conform to the statute and the distribution of resources determined by Congress in statute. Given the context of these provisions is a federal program, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions implementing the SUPPORT Act address the misuse and abuse of opioids in the manners directed by Congress. This includes the provisions related to Mandatory Drug Management Programs, Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs, Automatic Escalation to External Review under a Medicare Part D Drug Management Program for At-Risk Beneficiaries, Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures, Section 2008 of the SUPPORT Act, Section 6063 of the SUPPORT Act, Beneficiaries' Education on Opioid Alternatives, and Beneficiaries with Sickle Cell Disease. Given the context of these provisions is a federal program or impacts on several federal programs, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions which strengthen and improve the PACE program with respect to Service Delivery Request Processes under PACE improve the operation of government programs by ensuring documentation is available for oversight required by statute. Given the

context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.

- The provisions relating to Beneficiary Real Time Benefit Tools address inadequate and incomplete information available to Part D beneficiaries with regards to the choices they have for prescription drugs. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions relating to permitting a second, "preferred," specialty tier in Part D address externalities caused by the current specialty tier regulation – specifically the absence of negotiation leverage and incentives within the Part D specialty tier. Given the context of these provisions as a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions relating to the Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System improve the operation of government programs by making updates to reflect changes in measures (thereby ensuring the government program does not use outdated methodologies) and clarifying existing regulations (thereby answering questions regulated parties may have). These and other provisions also codify sub-regulatory guidance, which is an improvement in that regulated parties and CMS have greater clarity regarding the application of these policies as a rule. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.

2. Summary of the Major Provisions

a. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (hereinafter referred to as CARA) included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). Under the DMPs in place today, Part D sponsors engage in case management of

potential at-risk beneficiaries (PARBs) through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a beneficiary is determined to be at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit.

While the majority of Part D sponsors have already voluntarily implemented DMPs, CMS proposed regulations to implement section 2004 of the SUPPORT Act which require Part D sponsors to establish DMPs for plan years beginning on or after January 1, 2022.

CMS is finalizing the requirement for mandatory DMPs with an additional modification so that plans without a Pharmacy and Therapeutics (P&T) committee can comply with the DMP regulation.

b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[1] In light of this fact, in section 2006 of the SUPPORT Act, Congress required CMS to include Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) as PARBs under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, in lieu of modifying the definition of "potential at-risk beneficiary" at § 423.100 as proposed, CMS is finalizing the clinical guideline criteria at new paragraph § 423.153(f)(16)(ii)(2) to include a Part D eligible individual who is identified as having a history of opioid-related overdose, beginning January 1, 2022. Inclusion of beneficiaries with a history of opioid-related overdose as PARBs in DMPs will allow Part D plan sponsors and providers to work together to closely assess these beneficiaries' opioid use and determine whether any additional action is warranted. The clinical

[1] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193-1201. doi: 10.1111/add.13774.

guideline criteria CMS is finalizing at § 423.153(f)(16)(ii)(2) specify that both a principal diagnosis of opioid-related overdose and a recent Part D opioid prescription are required components to meet the definition of a PARB based on the history of opioid-related overdose. Additionally, CMS is making some revisions to the terminology used in the clinical guideline criteria at § 423.153(f)(16)(ii)(2) from what was initially proposed in the definition at § 423.100 to better characterize the data sources and opioid prescription criteria to be used to identify beneficiaries meeting the definition of a PARB based on a history of opioid-related overdose. The clinical guideline criteria mirror the definition of "potential at-risk beneficiary" that was initially proposed but relocated to § 423.153(f)(16)(ii)(2) to improve clarity of the regulation text.

c. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA-PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D-4(a)(1)(a) of the Act. Section 6102 of the SUPPORT Act amended section 1860D-4(a)(1)(B) of the Act to require that Part D sponsors also must disclose to each enrollee information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA-PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. Section 6102 also amended section 1860D-4(a)(1)(C) to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees rather than disclosing the information to each plan enrollee. We are finalizing our proposal with only one modification to make the requirement applicable beginning January 1, 2022, rather than January 1, 2021 as proposed.

d. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CMS proposed that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution by the expiration of the adjudication timeframe applicable to the plan level appeal. We also proposed conforming revisions to the notices that are sent to beneficiaries. In the February 2020 proposed rule, we solicited feedback on these proposals. As a result, we received several comments related to the timeframe in which a plan sponsor has to forward the case file to the IRE. Specifically, commenters requested that plan sponsors have additional time beyond the applicable adjudication timeframe in which to assemble and forward the administrative case file to the IRE. As a result of this feedback, we are finalizing the automatic escalation provision with a modification to reflect that plan sponsors must forward the case file to the independent outside entity no later than 24 hours following the expiration of the adjudication timeframe applicable to the plan level appeal. This approach is consistent with regulations applicable to cases that must be forwarded to the IRE if the plan sponsor is untimely in its decision making and, we believe, remains consistent with the enrollee protections set forth in the SUPPORT Act. We are also finalizing the provisions related to beneficiary notices. The following provisions of this final rule are applicable 60 days after the publication date of this final rule: §§ 423.590(i) and 423.600(b) related to auto-forwarding redeterminations made under a DMP to the IRE and the provisions related to information on appeal rights in the beneficiary notices at §§ 423.153(f)(5)(ii)(C)(*3*), 423.153(f)(6)(ii)(C)(*4*), and 423.153(f)(8)(i).

e. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

In the proposed rule, CMS proposed to undertake rulemaking to implement the provisions outlined in sections 2008 and 6063 of the SUPPORT Act, which are summarized in

the following sections (1) and (2). Implementing these provisions will allow CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA-PD plans) to share data and information regarding unscrupulous actors, take swift action based on such data and information, and achieve enhanced outcomes in our efforts to fight the opioid crisis. In addition, this regulation will provide the means for more effective referrals to law enforcement based on plan sponsor reporting, ultimately resulting in reduced beneficiary harm and greater savings for the Medicare program.

(1) Section 2008 of the SUPPORT Act

Title XVIII of the Social Security Act (the Act) provides authority for CMS to suspend payments to Medicare fee-for-service (FFS) providers and suppliers pending an investigation of a credible allegation of fraud, unless a good cause exception applies. While Part D plan sponsors currently have the discretion to suspend payments to pharmacies in the plans' networks, section 2008 requires that plan sponsors' payment suspensions based on credible allegations of fraud be implemented in the same manner as CMS implements such payment suspensions in FFS Medicare. Under this provision, plan sponsors are required to notify the Secretary of the imposition of a payment suspension that is based on a credible allegation of fraud and may do so using a secure website portal. The reporting requirement applicable to plan sponsors will only apply to suspended payments based on credible allegations of fraud as required by section 2008 and will not extend to other payment suspensions for which plan sponsors already have authority. Section 2008 also clarifies that a fraud hotline tip, without further evidence, is not considered a credible fraud allegation for payment suspension purposes. The statutory effective date for section 2008 is for plan years beginning on or after January 1, 2020.

(2) Section 6063 of the SUPPORT Act

Section 6063 requires, effective not later than 2 years after the date of enactment, the Secretary to establish a secure internet website portal to enable the sharing of data among MA plans, prescription drug plans, and the Secretary, and referrals of "substantiated or suspicious

activities" of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by eligible entities with a contract under section 1893 of the Act, such as a Medicare program integrity contractor. The Secretary is also required to use the portal to disseminate information to all MA plans and prescription drug plans on providers and suppliers that were referred to CMS for fraud, waste, and abuse in the last 12 months; were excluded or the subject of a payment suspension; are currently revoked from Medicare; or, for such plans that refer substantiated or suspicious activities to CMS, whether the related providers or suppliers were subject to administrative action for similar activities. The Secretary is required to define what constitutes substantiated or suspicious activities. Section 6063 specifies that a fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

Section 6063 also requires the Secretary to disseminate quarterly reports to MA plans and prescription drug plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the portal. The Secretary's reports are to maintain the anonymity of information submitted by plans and to include administrative actions, opioid overprescribing information, and other data the Secretary, in consultation with stakeholders, determines important.

Beginning with plan year 2021, section 6063 also requires Part D plan sponsors to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

The applicability date of the section 2008 and section 6063 provisions will be for plan years beginning on or after January 1, 2022 because of several factors. The first factor is the need to ensure that the web-based portal is complete and operational for plan sponsor's use. While the

development of the web-based portal began when the legislation was enacted, CMS was unable to complete the development of the portal in time for its full implementation in plan year 2021. In addition, the portal has required several key updates to reflect the requirements in this regulation. Additional factors include the time needed for plan sponsors to determine internal procedures to meet the requirements outlined in this rule; the need for CMS to obtain feedback from plan sponsors to address any challenges encountered with the web-based portal; and the need to provide plan sponsors with the opportunity to address any other operational challenges with implementing these provisions, including potential changes that may be needed due to the COVID-19 public health emergency. Furthermore, the applicability date is later than the effective dates in the SUPPORT Act because the publication of this final rule is occurring after the bid deadline for plan year 2021. However, where the statute is self-implementing, the delay in applicability of these regulations is not a barrier to enforcement of the statutory provisions.

f. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We have stated we will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time we are codifying additional existing rules for calculating the ratings used for MA Quality Bonus Payments, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns, and making additional technical clarifications. Unless otherwise stated,

data will be collected and performance measured using these rules and regulations for the 2022 measurement period and the 2024 Star Ratings.

g. Permitting a Second, "Preferred," Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We are finalizing regulations to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts drugs on these tiers from tiering exceptions to non-specialty tiers. Under this final rule, Part D sponsors will have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we will codify a maximum allowable cost sharing that would apply to the higher cost-sharing specialty tier. Further, we will require that if there are two specialty tiers, one must be a "preferred" tier that offers lower cost sharing than the proposed maximum allowable cost sharing.

We note that we did not propose to revise and are not revising § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. Because the exemption from tiering exceptions for specialty tier drugs under § 423.578(a)(6)(iii) as proposed would apply only to tiering exceptions to non-specialty tiers, the existing requirement at § 423.578(c)(3)(ii) will require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing, specialty tier.

To improve transparency, we will codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we will codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section IV.E.4. of this final rule. We determine the specialty-tier cost threshold – meaning whether the

drug has costs high enough to qualify for specialty tier placement – based on a 30-day equivalent supply. Additionally, we base the determination of the specialty-tier cost threshold on the ingredient cost reported on the prescription drug event (PDE). We will also maintain a specialty-tier cost threshold for both specialty tiers that is set at a level that, in general, reflects drugs with monthly ingredient costs that are in the top 1 percent, as described further in section IV.E.6. of this final rule. Finally, we will adjust the specialty-tier cost threshold, in an increment of not less than 10 percent, when an annual analysis of PDE data shows that an adjustment is necessary to recalibrate the specialty-tier cost threshold so that it only reflects Part D drugs with the top one percent of monthly ingredient costs. We will determine annually whether the adjustment would be triggered and announce the specialty-tier cost threshold annually via an HPMS memorandum or a comparable guidance document.

We are finalizing these provisions as proposed, except that we are not finalizing our proposal to specify a specialty-tier cost threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs. These provisions will apply for coverage year 2022.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will be in effect before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase "and biological products," and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their

exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

h. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

This rule finalizes regulations to require that Part D plan sponsors implement a beneficiary real-time benefit tool (RTBT) by January 1, 2023. The RTBT must allow enrollees to view the information included in the prescriber RTBT system, which will include accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). This rule permits plans to use existing secure patient portals to fulfill this requirement, to develop a new portal, or use a computer application. Plans are required to make this information available to enrollees who call the plan's customer service call center.

In order to encourage enrollees to use the beneficiary RTBT, plans are permitted to offer rewards and incentives (RI) to their enrollees who log onto the beneficiary RTBT or seek to access this information via the plan's customer service call center, provided the value of the RI offered is a reasonable amount.

i. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)

Currently, PACE participants or their designated representatives may request to initiate, eliminate or continue a service, and in response, the PACE organization must process this request under the requirements at § 460.104(d)(2). These requests are commonly referred to by CMS and the industry as "service delivery requests." In response to feedback from PACE organizations and advocacy groups, and based on our experience monitoring PACE organizations' compliance with our current requirements, we proposed moving the requirements for processing service delivery requests from § 460.104(d)(2) and adding them to a new § 460.121 in order to increase transparency for participants and reduce confusion for PACE organizations. We also proposed modifying these provisions in order to reduce unnecessary burden on PACE organizations and eliminate unnecessary barriers for participants who have

requested services that a PACE organization would be able to immediately approve. Specifically, we proposed to more clearly define what constitutes a service delivery request, and provide transparent requirements for how those requests would be processed by the PACE organization, including who can make a request, how a request can be made, and the timeframe for processing a service delivery request. We also proposed allowing the interdisciplinary team (IDT) to bypass the full processing of a service delivery request under the new proposed requirements in § 460.121 when the request can be approved in full by an IDT member at the time it is made. For all other service delivery requests that are brought to the IDT, we proposed maintaining the requirement that an in-person reassessment must be conducted prior to a service delivery request being denied, but we proposed eliminating the requirement that a reassessment (either in-person or through remote technology) be conducted when a service delivery request can be approved. Lastly, we proposed adding participant protections; specifically, we proposed increasing notification requirements in order to ensure participants understand why their request was denied, and we proposed adding reassessment criteria in order to ensure reassessments are meaningful to the service delivery request, and that the IDT takes them into consideration when rendering a decision.

We are finalizing these provisions as proposed, with some minor modifications. For example, all references to "service delivery requests" in §§ 460.104, 460.121 and 460.122 have been replaced with the term "service determination request." In addition, we have modified § 460.121(d)(2) to limit service determination requests to requests that are received by PACE organization employees and contractors who provide direct care in the participant's residence, the PACE center, or while transporting participants.

j. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)

Beneficiaries with active cancer-related pain, residing in a long-term care facility, or receiving hospice, palliative, or end-of-life care currently meet the definition of "exempt beneficiary" with respect to DMPs in § 423.100. Section 1860D-4(c)(5)(C)(ii)(III) of the Act

provides the Secretary with the authority to elect to treat other beneficiaries as exempted from DMPs. Due to concerns of misapplication of opioid restrictions in the sickle cell disease (SCD) patient population, CMS proposed that beneficiaries with SCD be classified as exempt beneficiaries. CMS is finalizing the definition of an exempted beneficiary to include beneficiaries with SCD as proposed with one modification to clarify that this definition is applicable starting in plan year 2022.

3. Summary of Costs and Benefits

Provision	Description	Primary Impact to Plans and Sponsors, Enrollees, and Medicare Trust Fund as applicable
a. Mandatory Drug Management Programs (DMPs) (§ 423.153)	This provision will codify the SUPPORT Act requirement making it mandatory that Part D sponsors implement DMPs, starting in plan year 2022.	There is a 10 year cost of $4.0 million. Part D sponsors will incur s a special first year cost of 3.2 million with ongoing costs of $0.1 million in later years.
b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)	As finalized, this provision will require that, starting in plan year 2022, CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse or misuse under sponsors' DMPs.	Part D beneficiaries with a history of opioid-related overdose have higher than average drug costs. CMS estimates that as a result of reduced utilization of drugs for beneficiaries participating in DMPs, there will be a savings of 5 percent of the current annual drug costs for enrollees with a history of opioid overuse. After the first year, the reduction in drug utilization may result in an annual savings of $7.7 million to the Medicare Trust Fund resulting from reduced drug spending by beneficiaries. The costs for case management and related paperwork is estimated at $10.1 million annually.
c. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)	CMS is finalizing requirements that Part D sponsors and MA-PDs must provide information on the risks of opioids and alternative therapies to all Part D beneficiaries with modification starting in plan year 2022.	The requirements set forth under 1860D-4(a)(1)(B) will cost approximately $0.5 million in the first year to account for one-time programming costs and $0.4 million in the following years.
d. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)	Under this final rule, if a Part D sponsor denies a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. A plan sponsor must forward the case to the independent outside entity no later than 24 hours following the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, this final rule establishes conforming revisions to the notices that are sent to beneficiaries.	We estimate there will be about 28,600 appeals per year, of which 0.08 percent will be denied and automatically escalated to the independent review entity (IRE). Therefore, there are approximately 23 cases (0.08 percent * 28,600) annually affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46, and typically an IRE will take at most 1 hour to review, the total burden is about $4,656.58 (23 cases * $202.46 * 1 hour).

e. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)	CMS is finalizing policies to implement two sections of the SUPPORT Act, which will-- (1) require Part D plan sponsors to notify the Secretary of the imposition of a payment suspension on pharmacies that is based on a credible allegation of fraud, impose such payment suspensions consistent with the manner in which CMS implements payment suspensions in fee-for service Medicare, and report such information using a secure website portal; (2) define inappropriate prescribing with respect to opioids; (3) require plan sponsors to submit to the Secretary information on investigations and other actions related to inappropriate opioid prescribing; (4) define "substantiated or suspicious activities" related to fraud, waste, or abuse; and (5) establish a secure portal which would enable the sharing of data and referrals of "substantiated or suspicious activities" related to fraud, waste, or abuse among plan sponsors, CMS, and CMS's program integrity contractors.	While we believe there may be savings generated through actions taken by plans that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS and plans sponsors, as well as additional law enforcement actions, we cannot estimate the impact at this time. The Part C and Part D sponsors will incur an initial aggregate cost of $15.2 million with level subsequent year aggregate costs of $9.6 million.
f. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)	We are codifying additional existing rules for calculating MA Quality Bonus Payments ratings, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns, and making additional technical clarifications.	There will be no, or negligible, impact on the Medicare Trust Fund from these provisions.
g. Permitting a Second, "Preferred," Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)	CMS is finalizing regulations to (1) allow Part D sponsors to establish a second, "preferred," specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty-tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either specialty tier.	Permitting Part D sponsors to establish a second, "preferred," specialty tier is unlikely to have a material impact on Part D costs to either the government or Part D enrollees.

h. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)	CMS is finalizing regulations to require that each Part D plan implement a beneficiary real time benefit tool by January 1, 2023. he RTBTl must enable enrollees to have the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements).	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on our estimates, we believe this will cost Part D plans about $4.0 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of $0.7 million in the first year, in order to implement the program, and $0.4 million in subsequent years in order to maintain the program. These are maximum impacts assuming all Part D sponsors choose to implement the rewards and incentives, and it remains to be seen whether or not this will be the case.
i. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)	CMS is finalizing the process by which PACE organizations address service determination requests. Currently the IDT must determine the appropriate member(s) of the IDT to conduct a reassessment, perform a reassessment, and render a decision on each service determination request. However, our experience shows that approximately 40 percent of all requests could be immediately approved in full by an IDT member. We are therefore removing the obligation for a request to be brought to the IDT or for a reassessment to be conducted when a member of the IDT receives and can approve a service determination request in full at the time it is made. We are also removing the requirement to conduct a reassessment in response to a service determination request except when a request would be partially or fully denied.	The proposed revisions create efficiencies which are estimated to create cost savings of $16.8 million in the first year and gradually increase to $ 21.3 million in 2031. The net savings over 10 years is $193.8 million. The savings are true savings to PACE organizations as a result of reduced administrative burden.
j. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)	CMS is finalizing that beneficiaries with SCD are classified as exempted from DMPs starting in plan year 2022.	We estimate that the impact of this provision is negligible because it will result in under 70 beneficiaries (i.e., beneficiaries with SCD who meet DMP inclusion criteria by meeting the definition of a PARB) being exempted from DMPs.

B. Background

We received approximately 667 timely pieces of correspondence containing multiple comments for the provisions implemented within this final rule from the proposed rule titled "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes

to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (February 2020 proposed rule). Comments were submitted by MA health plans, Part D sponsors, MA enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, and other vendor and professional associations. As mentioned previously, we are finalizing the policies from the February 2020 proposed rule in more than one final rule. The first part titled "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), and contained a subset of regulatory changes that impacted MA organizations and Part D sponsors more immediately, including information needed to submit their bids by the statutory deadline (the first Monday in June). The majority of the remaining provisions are addressed here in this final rule.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based on the comments received. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings.

We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. CMS did not make any proposals in the February 2020 proposed rule on these topics, and as such, these out-of-scope public comments are not addressed in this final rule. The following paragraphs summarize the out-of-scope public comments.

We received comments about how CMS will assess compliance with PACE regulatory requirements, recommendations for changes to PACE grievance requirements, and a

recommendation to require plan sponsors to automatically escalate all adverse Part D benefit appeals to the independent review entity. Related to Star Ratings, we received comments that CMS should only apply the Categorical Adjustment Index if it positively impacts a contract's Star Rating, and that we adopt completely new Star Ratings measures or change HEDIS measures during the COVID–19 pandemic. Related to establishing pharmacy performance measure reporting requirements, we received comments in favor of abolishing Direct and Indirect Remunerations, applying 100 percent of direct pharmacy price concessions at the point-of sale, prohibiting use of a scoring method that solely uses contractual pay-for-performance metrics, and the inclusion of clinical data as part of any standardized performance measures.

With regard to our proposals to permit Part D sponsors to maintain up to two specialty tiers, several commenters expressed that, in general, tiered-formulary structures have misaligned incentives, and that specialty tiers (particularly a second specialty tier), exacerbate the impact of such misaligned incentives. These commenters expressed concerns over the transparency of Part D rebate mechanisms and suggested that Part D sponsors have incentives to grant more expensive products with preferred status even when preferred products are not always the least expensive products, which the commenters posited increases costs for both Part D enrollees and the government. Some commenters suggested that CMS should eliminate the specialty tier, reasoning that elimination of the specialty tier would only produce modest increases in premiums and cost sharing in other tiers. Some commenters also suggested that the tiers should be relabeled and reordered in the hierarchy relative to Part D enrollee cost sharing to be more consistent with current industry practices. Some commenters suggested that CMS should mandate that denials at the pharmacy counter trigger the appeals process. Other commenters suggested that Part D enrollees stabilized on a specialty drug be exempt from unfavorable coverage changes (for example, increased cost sharing) resulting from a secondary specialty tier. Some commenters suggested that CMS should adjust the Part D rebate sharing formulas to remove plan incentives for high-cost, high-rebate brand drugs. Some commenters encouraged

CMS to investigate alternative catastrophic reinsurance models to incent the most savings for health plans implementing a preferred specialty tier. Some commenters suggested that, like private insurance plans with more than one specialty tier, CMS should establish an out-of-pocket max in Part D. Some commenters suggested a comprehensive reform of the Part D program. Some commenters suggested that transitioning to a biosimilar biological product on a lower specialty tier may have negative clinical implications for a patient stabilized on a reference product. (We refer readers to the Food and Drug Administration (FDA) regarding the safety and efficacy of biosimilar biological products, and their use in patients who have previously been treated with the reference product, as well as in patients who have not previously received the reference product.) Some commenters took the opportunity to suggest that CMS should expand the scope of our mid-year formulary change policy to include biosimilar biological products, reasoning that they are "equivalent" to the reference biological products. Some commenters suggested that CMS should improve the exceptions and appeal process. Some commenters suggested that CMS should ensure independent pharmacies cannot be excluded from providing non-preferred specialty tier drugs. Finally, some commenters suggested that CMS should institute conflict of interest provisions for pharmacy chains owned by PBMs. (We note that this rule, as we are finalizing it, would not provide Part D sponsors with any additional basis to exclude independent pharmacies from their networks.)

In response to proposed changes to the Coverage Gap Discount Program (CGDP), two commenters offered suggestions about how the Part D program could be more cost effective. One of these commenters urged CMS to prohibit Part D plans from using utilization management tools to steer utilization away from lower cost biosimilar products. The other commenter suggested that Congress change the CGDP in a way that would result in greater use of lower cost drugs throughout the program and suggested that the program's existence shifts the lower net cost determinations of generic and biosimilar products.

With regard to Medication Therapy Management (MTM), one commenter expressed concern about how pharmacists are paid for providing services, while another questioned the overall cost benefit of the MTM program.

A commenter recommended that CMS align exemption criteria for the Pharmacy Quality Alliance's Initial Opioid Prescribing Measures with DMP exemption criteria; however, these measures are not developed by CMS and are outside the scope of the proposed rule. We also received a number of comments that did not refer specifically to our Part D opioid proposals but more generally (1) referenced the opioid epidemic, (2) cited concerns that existing restrictions on opioid access may drive chronic pain patients to illicit markets and/or reduce their quality of life and functional status, (3) raised questions about Drug Enforcement Agency (DEA) actions against opioid prescribers and whether they address the root cause of the opioid epidemic, and (4) opined that interventions should be focused on illegal drugs.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

Congress authorized special needs plans (SNPs) as a type of Medicare Advantage (MA) plan designed to enroll individuals with special needs. The three types of SNPs are those designed for: (1) Institutionalized individuals (defined in § 422.2 as an individual continuously residing, or expecting to continuously reside, for 90 days or longer in specified facility) or institutionalized-equivalent (defined in § 422.2 as living in the community but requiring an institutional level of care, which is determined using a specified assessment instrument and conducted consistent with specified standards); (2) individuals entitled to medical assistance under a State Plan under title XIX of the Act; or (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP. As noted in the proposed rule (85 FR 9013 through 9014), there have been a number of changes to the requirements for MA SNPs since their initial authorization. We proposed changes to § 422.101(f) to implement and extend the latest of those statutory changes, made by the Bipartisan Budget Act of 2018 (BBA).

As of July 2019, there were 321 SNP contracts with 734 SNP plans that had at least 11 members. These figures included 208 Dual Eligible SNP contracts (D–SNPs) with 480 D–SNP plans with at least 11 members, 57 Institutional SNP contracts (I–SNPs) with 125 I–SNP plans with at least 11 members, and 56 Chronic or Disabling Condition SNP contracts (C–SNPs) with 129 C–SNP plans with at least 11 members. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).[2] The proposed rule summarized current processes and requirements for the models of care that all SNPs must use and follow under current law. (85 FR 9014)

[2] For more information pertaining to chapter 16b of the Medicare Managed Care Manual, please see: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.

The Bipartisan Budget Act of 2018 (BBA), enacted into law on February 9, 2018, amended section 1859(f) of the Act to include new care management requirements for C-SNPs. We proposed, and are finalizing here, regulations to implement the provisions of the BBA of 2018 and establishes new care management requirements at § 422.101(f) for all SNPs, including minimum benchmarks for SNP models of care. Due to operational considerations, the requirements we are finalizing at § 422.101(f) are intended for implementation for coverage beginning contract year 2023. Plans that are required to submit MOCs for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for the full implementation and enforcement of this final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

Specifically, we proposed the following:

• First, we proposed to implement the requirement in section 1859(f)(5)(B)(i) of the Act regarding the interdisciplinary team, or sometimes called the interdisciplinary care team (ICT), in an amendment to § 422.101(f)(1)(iii) that would require the team to include providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan, and in addition to implementing the statutory requirement for C-SNPs, extend the requirement to all SNPs.

• Second, we proposed to implement the requirement in section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee in a new paragraph (f)(1)(iv) of § 422.101 that would extend the requirement to all SNPs. Under our proposal, face-to-face encounters would have to be between each enrollee and a member of the enrollee's ICT or the plan's case management and

coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent; we also proposed that a face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter.

• Third, we proposed to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C-SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. As with the other provisions in section 1859(f)(5)(B) of the Act, we proposed to extend this requirement to the model of care for all SNPs, in revisions to § 422.101(f)(1)(i).

• Fourth, we proposed to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C-SNPs. We proposed a new provision at § 422.101(f)(3)(ii) to require that, as part of the evaluation and approval of the SNP model of care, National Committee for Quality Assurance (NCQA) must evaluate whether goals were fulfilled from the previous model of care. We also proposed, in new paragraphs (f)(3)(ii)(A) through (C) that: (A) plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals; (B) plans submitting a new model of care must provide relevant information pertaining to the MOC's goals for review and approval; and (C) if the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. We also proposed to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs must submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3)(i), using the same language.

• Lastly, we proposed to implement new regulation text at § 422.101(f)(3)(iii) to impose the requirement for benchmarks to be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C-

SNP model of care, and that the MOC can only be approved if each element meets a minimum benchmark. The proposed regulation in § 422.101(f)(3)(iii) would extend these benchmarks for all SNP models of care.

We proposed to extend the new requirements enacted by the BBA of 2018 to all SNP plan types for several reasons. We explained that these additional requirements are consistent with current regulations and sub-regulatory guidance CMS provides to all SNPs regarding care management and MOC compliance. Second, we believe that these proposed regulations are important safeguards to preserve the quality of care for all special needs individuals, including those enrolled in D-SNPs and I-SNPs and not just those enrolled in C-SNPs. Given the prevalence of medically complex chronic conditions among I-SNP and D-SNP enrollees, we believe the proper application of these new care improvement requirements would improve care for enrollees with complex chronic conditions. Finally, we stated that the application of multiple, different MOC standards would be operationally complex and burdensome for MA organizations that sponsor multiple SNP plan types, for instance, a D-SNP and a C-SNP. Our proposal would streamline operational and administrative obligations by making the different SNPs have similar requirements as well as establish minimum standards to benefit all special needs individuals in these plans.

In the proposed rule, we solicited comment on the extension of the new care management and MOC requirements for C-SNPs to the care management and MOC requirements for all SNP types and then discussed each of the specific proposed policies in turn. We address comments about the extension of the requirements to all SNP types first, followed by a review of each proposed policy and the relevant comments and the response to such comments. 1. Extension of the C-SNP requirements to all SNP types

Comment: CMS received a number of comments in support of or in opposition to the extension of C-SNP requirements, added to section 1859(f)(5) of the Act by the BBA of 2018, to apply to all SNP types, instead of limiting the applicability of these requirement to just C-SNPs.

A handful of commenters were concerned about the applicability of several of the proposed regulations to I-SNP and D-SNP care management protocols with some arguing that the proposed rule would result in requirements that are duplicative of the current MOC approval process requirements. Several commenters specifically noted that SNPs of all types have existing processes and practices that cover the areas discussed in the proposed rule. They contend that the NCQA Model of Care, review, and scoring guidelines comprehensively cover the coordination of care, provider, and quality requirements outlined in the proposed rule. In addition, commenters noted that CMS audits include review of performance by SNPs on these processes.

Response: Regarding the extension of section 1859(f)(5) of the Act to include all SNP types, we agree this rule is consistent with current CMS policy, including several current regulations implementing section 1859; the statute and several regulations establish similar requirements for all SNPs regardless of type. Specifically, section 1859(f)(5)(A) of the Act requires that MA organizations offering a SNP implement an evidence-based model of care. The MOC and other SNP-specific requirements have been incorporated into the MA application for MAOs that wish to offer a SNP so that these MAOs can demonstrate that they meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs. In the Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions (74 FR 1493), known hereafter as the January 2009 final rule, CMS outlined the overarching purpose of section 422.101(f) and noted that SNPs, regardless of type, are required to meet the same requirements including that each plan must have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to people with disabilities, frail older adults, and those near the end of life based on appropriate protocols. (74 FR 1498 through 1450) CMS's belief that these measures are critical to providing care to the types of special needs populations served by SNPs has not changed in the intervening years since finalizing § 422.101(f) in 2009. As noted in this section of this rule,

for each specific provision we proposed and are finalizing at § 422.101(f), CMS is codifying certain requirements that are part of the current SNP MOC approval process. Rather than forcing a duplication of processes, we believe that SNPs have already implemented many of these new requirements into their MOC. Understanding this, we proposed and are finalizing these provisions in line with current MOC review and scoring guidelines, covering all facets of the MOC including care coordination, provider, and quality requirements.

As discussed in the proposed rule, extending the statutory requirements for C-SNPs to all SNPs will provide improvements to the care coordination model in all SNPs. For example, section 1859(f)(5)(B)(ii), as added by the BBA of 2018, requires C-SNPs to provide face-to-face encounters with each enrollee on an annual basis, consistent with standards adopted by CMS. We proposed and are finalizing, at § 422.101(f)(1)(iv), that all SNPs provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. Face-to-face encounters are appropriate to require for all SNP enrollees because these SNP enrollees have similar healthcare needs, including the need for treatment of multiple chronic conditions and for services such as care coordination.

Comment: Another comment supported the proposal, but added that CMS should explore the application of a more rigorous set of requirements focused on person-centered care to strengthen the MOC and meet the needs of SNP enrollees.

Response: We thank the commenter for their comment and suggestions. As proposed and finalized, the new provisions in § 422.101(f) provide both a structure for creating a care management process specifically designed to provide targeted care to individuals with special needs and allow flexibilities enabling plans to create innovative approaches to person-centered care. As noted in the Interim Final Rule with comment, titled "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs" (CMS-4138-IFC), issued in

September 2008 (“September 2008 IFC”) (73 FR 54225, 54228), we expect the MA organizations that have the commitment and resources to serve vulnerable special needs beneficiaries through SNPs will perpetually evaluate their own model of care by collecting and analyzing performance data to continually improve their model of care. We also noted in the September 2008 IFC that CMS would continue to evaluate models of care through the analysis of SNP performance data and monitoring visits, the review of scientific research on the efficacy of other care models, and feedback from beneficiaries, advocacy groups, and healthcare professionals (73 FR 54228). The revisions to § 422.101(f) adopted in this final rule represent a continuation of this process to evaluate and refine SNP care management.

This final rule establishes and clarifies delivery of care standards for SNPs and codifies standards which we have included in other CMS guidance and instructions. As such, we are finalizing the revisions to paragraph (f) to § 422.101 generally as proposed to extend certain statutory requirements to all SNPs.

1. The Interdisciplinary Team (ICT) in the Management of Care

As amended by the BBA of 2018, section 1859(f)(5)(B)(i) of the Act requires the interdisciplinary team (ICT) of each C-SNP to include providers with specified expertise and training. We proposed to implement this through an amendment to § 422.101(f)(1)(iii) that would apply the requirement to all SNPs. We proposed to require that each MA organization offering a SNP plan must provide each enrollee with an ICT that includes providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

We explained in the proposed rule that MIPPA required SNPs to conduct initial and annual comprehensive health risk assessments, develop and implement an individualized plan of care, and implement an ICT for each beneficiary. Specifically, Section 1859(f)(5)(A)(ii)(III) of the Act requires all SNPs to use ICTs as part of offering a specialized MA plan for special needs individuals. As stated in the proposed rule, we believe that the combination of MIPPA's statutory

elements and our regulatory prescription for the SNP model of care establishes a standardized architecture for effective care management while giving plans the flexibility to design the unique services and benefits that enable them to meet the needs and preferences of their target population. We believe our proposal, which amends paragraph (f)(1)(iii) and applies the additional requirements pertaining to demonstrated expertise and training of interdisciplinary team providers to all SNPs, is consistent with the MIPPA requirements and the rulemakings that first adopted requirements for the use of interdisciplinary teams (73 FR 54228, 74 FR 1498).

All SNPs must have an ICT to coordinate the delivery of services and benefits, but the current regulation provides flexibility as necessary for each SNP: one SNP may choose to contract with an ICT to deliver care in community health clinics; and another SNP may hire its team to deliver care in the home setting. Under the current rule, and our proposal, all SNPs must coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries. However, as we explained in the proposed rule, one SNP may coordinate care through a telephonic connection among all stakeholders and another SNP may coordinate care through an electronic system using Web-based records and electronic mail accessed exclusively by the plan, network providers, and beneficiaries. All SNPs must coordinate the delivery of specialized benefits and services that meet the needs of their most vulnerable beneficiaries. However, D-SNPs may need to coordinate Medicaid services while an institutional SNP may need to facilitate hospice care for its beneficiaries near the end of life. We provided these examples in the proposed rule to demonstrate the variety of ways SNPs currently implement their systems of care and how we believe all SNP enrollees should have access to a team of providers with expertise and training that are appropriate for each individual enrollee.

We received the following comments and our responses follow:

Comment: A commenter recommended that CMS clarify that "providers," as used in this section, follows the definition of "provider" in 42 CFR 422.2, and also recommended that CMS

provide additional details about what constitutes "demonstrated expertise and training." Specifically, the commenter requested that CMS clarify whether there are minimal expertise or training requirements that the provider must meet or whether each special needs plan would have discretion to make this determination.

Response: As proposed and finalized, § 422.101(f)(1)(iii) requires SNPs to use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan. Our current guidance for the MOC approval process provides that a SNP's MOC describe the composition of the ICT, including how the SNP determines ICT membership and the roles and responsibilities of each member. Additional information can be found in Chapter 5 of the MMCM, section 20.2.2, specifically guidance on MOC 2, Element D.[3] A compliant and well-developed MOC includes a description that specifies how the expertise and capabilities of the ICT members align with the identified clinical and social needs of the SNP beneficiaries. As proposed and as finalized, the requirement in § 422.101(f)(1)(iii) to have training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan means that individual providers and providers in one type of SNP (compared to other SNPs) may have training and expertise that differ based on the SNP-type or each individual enrollee's needs. For example, a C-SNP that targets diabetes mellitus may seek to establish an ICT for each enrollee that has a specialist with training and expertise in endocrinology while a D-SNP may want to establish ICTs for individual enrollees that focus on a particular set of chronic conditions or focus on specific service delivery needs for an enrollee, such as long-term services and supports. This is consistent with our current guidance and we believe that any additional burden here for SNPs will be minimal.

[3] Please see Chapter 5 of the MMCM, which can be found at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c05.pdf

As defined in § 422.2, a provider is: (1) an individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; or (2) an entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. Therefore, the providers in the ICT must be licensed or certified to furnish the health care services they deliver. Under this new regulation, providers in an ICT must also be trained in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan, when applicable. We expect that plans are already meeting this requirement that members of the ICT have training and expertise specific to the SNP's target population based on MOC scoring guidelines provided to all SNPs by NCQA; for example, MOC submissions specify how the expertise and capabilities of the ICT members align with the identified clinical and social needs of the SNP enrollees and describe how specific care plans for enrollees are used to determine the composition of the ICT.[4] In conclusion, under the amendment to paragraph (f)(1)(iii) that we are finalizing here, all members of the ICT must be licensed or certified to deliver the applicable health care furnished to enrollees of the SNP in compliance with § 422.2 and all of the members of the ICT must have demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan. The revisions at § 422.101(f)(1)(iii) are being finalized as applicable beginning with 2023 so MOCs for that period will be reviewed and approved based on demonstrated compliance with this final rule. The specifics of the expertise and necessary training will vary with the SNP and the covered population, and we are not adopting specific, uniform minimum requirements for all providers in all SNPs ICTs.

[4] The scoring guidelines can be found at: https://snpmoc.ncqa.org/wp-content/uploads/MOC-Scoring-Guidelines_CY-2021-1.pdf. See section MOC 2, Element D.

The revisions at § 422.101(f)(1)(iii) are being finalized as applicable beginning 2023 so MOCs for that period and subsequent years will be reviewed and approved based on demonstrated compliance with the amendments to the regulation that we are finalizing here.

Comment: CMS received several comments regarding the extension of the new statutory interdisciplinary team requirements to D-SNPs and I-SNPs. Some commenters believed that plan implementation of additional ICT requirements would be unnecessarily burdensome because some D-SNPs have difficulty contracting with and requiring specialists to take part in the ICT process. Other commenters noted that the new rule would be redundant, given existing regulations and policies are already in place, including regulations applying to the institutional settings in which I-SNP beneficiaries reside. Some of these commenters noted that adding ICT requirements will increase the burden on long-term care facilities and may require some patients to be managed to different standards than others. Others noted that this provision could interfere with plans' current practices that promote the identification of providers from disciplines that are most relevant to the beneficiary's needs. Another commenter noted that for D-SNPs, there are credentialing and network adequacy standards already in place to ensure appropriate access for D-SNP enrollees to high-quality providers. Lastly, CMS received a comment stating that the ICT should include the enrollee's managed care long term services and supports (MLTSS) care manager in cases where the enrollee receives those services.

Response: We believe the revisions we proposed and are finalizing at § 422.101(f)(1)(iii) are consistent with the current review and approval process for each MOC submission under MOC 2, Element D. While there might be overlap and redundancies for § 422.101(f)(1)(iii) and existing standards either for SNPs and SNP MOCs or for institutional providers that furnish services to SNP enrollees, that only reinforces that finalizing § 422.101(f)(1)(iii) as proposed is appropriate. As SNPs are designed to furnish services and coordinate care based on the needs of its target population, ensuring that the providers and ICT that deliver that care have expertise that is specific to the target population is consistent with the overall goals of SNPs.

As noted in Chapter 5 of the MMCM, section 20.2.2, the role and conditions of MOC approval for the ICT are described in MOC 2 Element D. All SNPs are required in § 422.101(f) to implement an evidence based model of care (MOC) that has been evaluated and approved by the NCQA. As part of the approval process, SNPs are also required to meet ICT requirements under Element D. Each SNP must describe how its organization determines the composition of ICT membership. Under factor 1 of MOC 2, Element D, all SNPs must explain how the SNP facilitates the participation of beneficiaries and their caregiver(s) as members of the ICT. In addition, each SNP must describe how the beneficiary's Health Risk Assessment Tool (HRAT) and ICP are used to determine the composition of the ICT for each enrollee, including where additional team members are needed to meet the unique needs of a beneficiary. Lastly, SNPs must explain how the ICT uses health care outcomes to evaluate processes established to manage changes or adjustments to the beneficiary's health care needs on a continuous basis. The new regulation text concerning the ICT and the need to include providers with certain expertise and training are similar to these existing requirements and standards for the MOC, so any additional burden should be minimal. To the extent that a SNP is already using the needs and assessments of each enrollee to identify ICT members that are qualified and trained to meet that individual enrollee's unique needs (and does this for each enrollee), this new standard may require some additional documentation from the SNP about the demonstrated expertise, licensure and training of the ICT. CMS believes plans will be able to implement the new ICT provisions without significant changes to current processes based on two critical factors: (1) all SNPs are already required under § 422.101(f)(1)(iii) to establish an ICT for each enrollee, and thus, plans have in place steps for reviewing ICT composition and qualification; and (2) more importantly, SNPs are currently employing a process similar to the new provision for establishing an ICT as part of the MOC application approval process. Again, the new ICT provision is a natural extension of and generally codifies elements of the current MOC approval process covering the ICT, which should facilitate a seamless transition for SNPs as they implement the necessary processes to

comply with new ICT requirements. These changes to the MOC, and the others contained in the amendments to § 422.101(f) will apply to MOCs and SNP performance for 2023. This means that SNPs submitting MOCs for 2023 will need to develop and implement their MOCs for 2023 based on the amendments in this final rule. However, CMS will not require SNPs that currently employ MOCs that have been approved by NCQA and are not due for review and approval in 2023 to resubmit their MOCs to demonstrate compliance with § 422.101(f)(1)(iii) as amended in this rule; so long as the SNP and its MOC meets all other requirements, the SNP may continue to operate under its current MOC based on how similar the ICT provision of this final rule is to current law and policy. We strongly encourage D-SNPs and I-SNPs that do not have MOCs up for review and approval for 2023 to review their MOCs and implement changes as necessary to ensure the interdisciplinary team for each enrollee includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

While the commenter states that some SNPs may face obstacles when seeking ICT participation from some providers (including certain types of specialists), CMS has not seen evidence suggesting such difficulties. Due to the similarity of § 422.101(f)(1)(iii) as revised in this rule to CMS's current policy and the standards used in NCQA reviews, it is likely that any difficulty that would lead to an inability to comply with this provision would have been apparent in past reviews of MOCs.

As we noted in the preamble of the proposed rule, SNPs are in the best position to identify an ICT with the appropriate expertise and training necessary to meet the clinical needs for each enrollee, based on the medical and behavioral health conditions of their member population and the SNP's developed expertise. We expect that an MA organization that offers a SNP for a particular population based on a chronic condition, on residence in an institution or needing a similar level of care as those who reside in an institution, or on eligibility for both Medicare and Medicaid, will have considered the needs of such populations in designing the plan

and the network of providers. MA organizations are not required to offer SNPs and those that choose to do so must be capable of meeting the unique needs of the targeted population, including gaining the participation of specialists and other health care providers that have the most or best expertise for serving these vulnerable populations, consistent with the regulatory requirements. With respect to the inclusion of the enrollee's MLTSS care manager, we again defer to SNPs to determine the appropriate composition of the beneficiary's ICT in compliance with the MOC standards, which includes consultation with the beneficiary. This final rule is based on and reflects a policy that while all SNPs must develop and use an ICT to coordinate the delivery of services and benefits for each enrollee, the construction of the ICT must recognize and be built to address the needs and wishes of each individual enrollee.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(1)(iii) regarding ICT expertise and training as proposed without modification.

2. Face-to-Face Annual Encounters

We proposed to implement section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee. We proposed that the face-to-face encounter be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent. We also proposed to codify that a face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter. We proposed to adopt this in a new paragraph (f)(1)(iv) in § 422.101 that would extend the requirement to all SNPs. Under our proposal, SNPs would be required to provide an annual face-to-face visit that is in-person or by remote technology and occurs starting within the first 12 months of enrollment within the plan. For instance, a plan enrolling a beneficiary on October 1 would need to facilitate a face-to-face encounter with that enrollee by September 30th of the following year. We indicated in the

proposed rule that SNPs should implement this requirement in a manner that honors any enrollee's decision not to participate in any qualifying encounter.

We received the following comments and our responses follow:

Comment: CMS received a number of comments both supporting and opposing the requirement for SNPs to provide a face-to-face encounter with each enrollee. Some plans noted that this is already part of their program. Some commenters, however, were concerned that implementation could be a burden for enrollees, while others were concerned that the requirements would be particularly difficult for SNP types with larger enrollments, such as D-SNPs. Still others believed that the new regulation would be hard for plans to track encounters between enrollees and providers. Others suggested that CMS allow SNPs to use encounters with non-ICT plan contracted providers to meet this requirement.

Response: We are finalizing the proposal to add § 422.101(f)(1)(iv) to require each SNP to provide an annual face-to-face encounter with each enrollee, with some modifications to address concerns raised by the commenters. As proposed and finalized, the required face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter. The final rule requires, as proposed, that the MA organization provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff. And finally, we are also finalizing that the face-to-face encounter occur on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. However, we are finalizing additional flexibility as well for SNPs in connection with § 422.101(f)(1)(iv) by including that the required face-to-face encounter may also be with a contracted health plan provider and clarification as to the type of encounter that is required.

As we noted in the proposed rule, we intend for this requirement to be met in a number of different ways. In the proposed rule, we provided examples of encounters that would meet the requirement, including a visit to or by a member of an individual's interdisciplinary team or the

plan's case management and coordination staff that perform clinical functions, such as direct beneficiary care. We agree with commenters that have requested that encounters with health care providers contracted with the enrollee's SNP qualify under the implementation of the final rule. This would include the enrollee's regular primary care physician, a specialist related to the enrollee's chronic condition, a behavioral health provider, health educator, social worker, and MLTSS plan staff or related MLTSS health care providers provided that such providers are (i) a member of the enrollee's interdisciplinary team; (ii) part of the plan's case management and coordination staff; or (iii) contracted plan healthcare providers. Requiring at a minimum that a healthcare provider with a contractual relationship with the SNP be part of the annual face-to-face encounter in this way will ensure that the annual encounter is a meaningful one from the perspective of the enrollee's overall health and wellbeing. We also believe that a healthcare provider with a contractual relationship will facilitate the sharing of critical health information among the plan, the ICT, and other key healthcare providers, and thus ensure coordination of care for the enrollee under § 422.112(b), and result in increased care coordination and facilitate any necessary follow-up care or referrals. Therefore, we are finalizing the new regulation at § 422.101(f)(1)(iv) with additional text to list contracted plan healthcare providers as well as members of the ICT and the plan's care coordination team. We defer to each SNP to identify which providers are part of the plan's case management and coordination staff or contracted plan healthcare providers so long as the SNP's policies are reasonable and not a means to evade compliance with the rule.

We intend for this mandatory face-to-face encounter to serve a clinical or care coordination/care management purpose. Ensuring that a special needs individual has been contacted by the SNP at least once a year and that there has been a face-to-face encounter that pertains to the individual's health care is a way of ensuring that the goals of a SNP are met. Examples of the necessary services or engagement happening during the required encounter include: (i) engaging with the enrollee to manage, treat and oversee (or coordinate) their health

care (such as furnishing preventive care included in the individualized care plan (ICP)); (ii) annual wellness visits and/or physicals; (iii) completion of a health risk assessment (HRA), such as the one annually required for all SNPs under the current regulation at § 422.101(f)(1); (iv) care plan review or other similar care coordination activities; or (v) health related education whereby the enrollee receives information or instructions critical to the maintenance of their health or implementing processes for maintaining the enrollee's health, such as the administration of a medication. These examples are not the only activities that satisfy the new regulatory requirement. Encounters may also address any concerns related to the enrollee's physical, mental/behavioral health, or overall health status, including functional status. Plans may also use qualifying encounters – those that meet qualifications as stipulated in this final rule – that are the result of plan efforts to satisfy state-mandated Medicaid or MTLSS requirements. We believe many SNPs would already meet this standard in current practice and have sufficient encounters on at least an annual basis with each enrollee that this new regulation will not be burdensome. Encounters that are sufficient to meet the regulatory requirement we are finalizing could occur either through regular visits by the enrollee to a member of the beneficiary's interdisciplinary team or through the care coordination process established by the plan's staff or contracted plan healthcare providers. We anticipate that, consistent with good clinical practice, concerns are addressed and any appropriate referrals, follow-up, and care coordination activities provided or scheduled as necessary as a result of these face-to-face encounters.

We are cognizant that enrollees should have the final authority over their health care and our proposed regulation text reflected this by requiring that these face-to-face encounters be as feasible and with the enrollee's consent. A SNP must comply with this requirement in a manner that honors any enrollee's decision not to participate in a face-to-face (either in-person or virtual) encounter. If an enrollee does not consent to the encounter required by § 422.101(f)(1)(iv), the plan should document that in order to demonstrate compliance with the regulation. The rule addresses feasibility barriers to a SNP providing for the required annual encounter, such as

where a SNP enrollee may be non-responsive to plan outreach or the state of the member's health (such as if the member is dealing with a hospitalization) prohibits a face-to-face encounter with the type of provider or staff that are described in the final regulation. In these circumstances, CMS recognizes that a SNP may not be able to comply with the rule's mandate of an annual face-to-face encounter and we intend the "as feasible" standard in the regulation to address such situations. Since the enrollee has refused or because the SNP could not reach the enrollee after reasonable attempts, the plan has complied with the requirement despite the lack of a qualified encounter. However, plans should document the basis or reason that a face-to-face encounter is not feasible in order to demonstrate that where there are no face-to-face encounters in the year, that failure is not a violation of the regulation. Note that a feasibility barrier does not include a SNP having to provide a reasonable accommodation, such as interpreter services, in order for the enrollee to participate in the encounter.

Lastly, restricting the manner of face-to-face encounters to those that are in-person or as a visual, real-time, interactive telehealth encounter is consistent with section 1859(f)(5)(B)(ii) of the Act as amended by section 50311 of the Bipartisan Budget Act of 2018. The statute requires CMS to set requirements for face-to-face encounters that must happen on an annual basis for C-SNPs; and in extending that requirement to I-SNPs and D-SNPs, we do not believe there is reason to develop different standards. For this specific requirement, we believe that a real-time, interactive, visual telehealth encounter permits face-to-face interaction even though electronic or telecommunications technology is used to facilitate the encounter. The real-time, interactive, visual encounter serves the same function and permits sufficiently similar engagement between the enrollee and the required member of the ICT, the SNP's case management or care coordination staff, or other contracted provider of the SNP as an in-person encounter for purposes of this specific requirement; our regulation here does not address when or how telehealth encounters may be clinically appropriate or sufficient but only specifically addresses the need for SNPs to ensure there is one annual encounter of a certain type for each enrollee.

While not all covered services are necessarily appropriate to furnish through electronic means, MA plans (including SNPs) have broader flexibility in this regard under § 422.135. Therefore, face-to-face encounters required for all SNPs under this new rule may include visual, real-time, interactive telehealth encounters. As we noted in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Final Rule (hereinafter referred to as the April 2019 final rule), we believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Comment: A few commenters suggested that in the implementation of the face-to-face encounter requirement that SNPs should be allowed to develop their own technical specifications for capturing compliance with this requirement. For example, An MAO recommended that SNPs be allowed to capture verbal confirmation from members or providers of completed face-to-face encounters from external parties and/or telehealth encounters as evidence of compliance.

Response: CMS believes plans are in the best position to develop the processes and technical specifications for documenting how they meet this requirement and that a face-to-face encounter for purpose of satisfying this regulation has taken place. While § 422.101(f)(1)(iv) imposes some parameters for these encounters, there is a broad range of flexibility for how SNPs may meet the requirement. However, we clarify that our guidance here is specific to § 422.101(f)(1)(iv) and does not address any other Medicare program requirements. Because an encounter must pertain to the delivery of health care to the enrollee, we encourage SNPs to take the information from these encounters into account and to document them consistent with how other health care visits are documented. Lastly, CMS will monitor compliance with the requirement and consider additional rulemaking if necessary.

Comment: Several commenters suggested the addition of the face-to-face requirement would create additional reporting burden for plans associated with capturing compliance to the rule.

Response: We are also cognizant that new regulations sometimes include additional reporting or record keeping requirements. The final rule does not create any additional, explicit reporting requirements. However, SNPs are required under § 422.503(b)(4)(vi) to adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. CMS will be monitoring compliance by SNPs with this requirement. In addition, SNPs should have information about all health care encounters and deliveries of covered services for many purposes, including: payment to providers for furnishing services; complying with the existing data submission requirements in § 422.310; and meeting the requirements of § 422.112(b)(4), which requires procedures for plans and their provider networks to have the information necessary for effective and continuous patient care and quality review.

Comment: Several commenters stated that some enrollees lack access to technology that would provide visual, real-time, interactive telehealth encounter, which may create a barrier to beneficiary participation in such encounters. Others requested that CMS allow telephonic encounters to count towards the annual face-to-face requirement under the new regulation.

Response: We are cognizant that enrollees should have the final authority over their health care and our proposed regulation text reflected this by requiring that these face-to-face encounters be as feasible and with the enrollee's consent. First, SNPs have the flexibility to meet the requirement for a face-to-face encounter, either in-person or virtually. We believe that many beneficiaries are already meeting the requirement through in-person face-to-face encounters with qualified healthcare providers, which we believe will create minimal additional burden for plans implementing this final rule. The final rule does not mandate that SNPs utilize a visual, real-time,

interactive telehealth encounter, though it is a permissible option when appropriate. Second, the SNP must comply with this requirement in a manner that honors any enrollee's decision not to participate in a face-to-face (either in-person or virtual) encounter. If an enrollee does not consent to the encounter required by § 422.101(f)(1)(iv), the plan should document that in order to demonstrate compliance with the regulation. The rule addresses feasibility barriers to a SNP providing for the required annual encounter, such as where a SNP enrollee may be non-responsive to plan outreach or the state of the member's health (such as if the member is dealing with a hospitalization in an out-of-network facility) prohibits a face-to-face encounter. In these circumstances, CMS recognizes that a SNP may not be able to comply with the rule's mandate of an annual face-to-face encounter and we intend the "as feasible" standard in the regulation to address such situations. By clarifying that a face-to-face encounter for delivery of health care services by a contracted provider will satisfy this requirement, it seems likely that most SNPs will be able to meet this requirement for most enrollees, as most enrollees in SNPs receive health care services at some point each year. If the enrollee has refused or because the SNP could not reach the enrollee after reasonable attempts, the plan would be considered to have complied with the requirement despite the lack of a qualified encounter.

This final rule allows many types of face-to-face encounters, including visual, real-time, interactive telehealth encounters, to suffice for meeting the requirement. We do not believe that telephonic encounters should count towards the fulfilling the requirements of § 422.101(f)(1)(iv) for several reasons. First, the statute at section 1859(f)(5)(B)(ii) of the Act is specific in requiring that the encounters provided annually must be face-to-face with individuals enrolled in the plan. An audio-only encounter does not meet the statutory requirement that the encounter be face-to-face. Even though the statutory requirement is for C-SNPs, we believe that requiring all SNPs to meet this standard is appropriate in light of the health care needs and characteristics of the other populations of special needs individuals. Second, an audio-only encounter does not permit the provider to see the patient to use visual clues (for example, bruising, physical symptoms, or lack

of focus) that could indicate something is wrong with the patient. This is a requirement for only one visit of this type a year and does not prohibit the use of audio-only encounters when those are appropriate for addressing other health care needs or visits. Further, for enrollees who do not use telehealth or lack the technological resources for such encounters, in-person delivery of health care services from one of the types of providers described in the regulation satisfies this requirement; there is no requirement for telehealth-based encounters to be used instead of in-person encounters. However, we will continue to monitor the ability of beneficiaries to take part in virtual encounters, the applicability of non-telephonic face-to-face encounters, and to assess the adequacy of substituting telephonic encounters in addition to the set of qualifying face-to-face encounters for I-SNPs and D-SNPs through future rulemaking.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing § 422.101(f)(1)(iv) regarding face-to-face encounters substantially as proposed, but with modifications to clarify that the required face-to-face encounters pertain to the delivery of certain kinds of services (health care or care coordination services or care management) and must be with a contracted health care provider or certain SNP staff (a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff). In addition, our final regulation text at paragraph (f)(1)(iv) is somewhat reorganized from the proposed rule to improve the readability of the provision.

3. Health Risk Assessments and the SNP Enrollee's Individualized Care Plan

We proposed to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C-SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. We also proposed to extend this requirement to the model of care for all SNPs in revisions to § 422.101(f)(1)(i). Currently, MA organizations offering SNPs must conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as an annual HRA, using a comprehensive risk assessment tool that CMS may review

during oversight activities. The proposed revision to paragraph (f)(1)(i) would also require the MA organization to ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii).

We received the following comments and our responses follow:

Comment: Several commenters sought clarification concerning what type of information must be included in the ICP from the HRA. In addition, a few commenters wanted to know what information plans could omit from the ICP while adhering to the regulation. Another commenter asked if D-SNPs would be permitted to align the HRA with other beneficiary assessments that some D-SNPs are required to submit for a state's requirement that enrollees be assessed as to Medicaid managed long-term services and supports (MLTSS) needs.

Response: Existing CMS guidance addresses the first part of these comments – pertaining to the information from the HRA that must be incorporated into the ICP –and that guidance is consistent with the regulatory provision being finalized at § 422.101(f)(1)(i). Chapter 5 of the Medicare Managed Care Manual, section 20.2.2, addresses how each SNP's MOC includes a clear and detailed description of the policies and procedures for completing the health risk assessment tool (HRAT).[5] Because this existing guidance adequately describes how information from the annual HRA is incorporated into the enrollee's ICP, the guidance remains applicable. Part of NCQA's review of SNP MOCs is an evaluation of MOC 2, Element B, which includes the following subfactors:

- How the organization uses the HRAT to develop and update the Individualized Care Plan (ICP) for each beneficiary (Element 2C).
- How the organization disseminates the HRAT information to the Interdisciplinary Care Team (ICT) and how the ICT uses that information (Element 2D).

[5] Please see Chapter 5 of the MMCM, which can be found at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c05.pdf

• How the organization conducts the initial HRAT and annual reassessment for each beneficiary.

• The detailed plan and rationale for reviewing, analyzing and stratifying (if applicable), the HRA results.

Under Element B, the content of and methods used to conduct the HRAT have a direct effect on the development of the ICP and ongoing coordination of ICT activities. The HRAT must assess the medical, functional, cognitive, psychosocial and mental health needs of each SNP beneficiary, as noted in Chapter 5 of the MMCM, section 20.2.2.

To meet the requirements of the first 2 factors of MOC 2, Element B, the SNP's MOC must include a description of how the HRAT is used to develop and update, in a timely manner, the ICP for each beneficiary and how the HRAT information is disseminated to and used by the ICT. Under factor 3, the description must include the methodology used to coordinate the initial and annual HRAT for each beneficiary (for example, mailed questionnaire, in-person assessment, phone interview) and the timing of the assessments. There must be a provision in the MOC for reassessing beneficiaries if and when warranted by a health status change or care transition (for example, hospitalization or a change in medication. The SNP must describe in the MOC the SNP's process for attempting to contact beneficiaries and have them complete the HRAT, including provisions for beneficiaries that cannot or do not want to be contacted or complete the HRAT. This approach in our current guidance provides plans the flexibility to develop an ICP that is appropriate for each beneficiary based on and using HRA information; the requirement added to § 422.101(f)(1)(i) that each SNP ensure that results from the initial assessment and annual reassessment conducted for each enrollee are addressed in the individual's individualized care plan would be met by a SNP that does these things in its development of the MOC and the ICP. CMS intends to implement and enforce the revisions to § 422.101(f)(1)(i) consistent with existing CMS guidance regarding the information from the HRA and HRAT that must be incorporated into the ICP.

We understand that some D-SNPs may be required to complete and use other assessments related to the Medicaid program. Integrated D-SNPs may choose to combine Medicaid and Medicare assessments as long as the assessment includes a review of the medical, functional, cognitive, psychosocial and mental health needs of each SNP beneficiary and is described in the MOC. Other assessments may (or may not) require the same elements or scope as the HRA required of MA SNPs so alignment and overlap of the assessments and how they are used depends on the specifics of each situation. As we implement § 422.101(f)(1)(i), we will continue to monitor the alignment of multiple assessments on SNP enrollees to determine whether further rulemaking is necessary. However, plans have created an HRA process as part of their approved MOC in the past, so we do not anticipate that SNPs will have difficulty complying with the changes we are finalizing to § 422.101(f)(1)(i). To the extent that there is overlap and the HRA required by § 422.101(f)(1)(ii) can be aligned with other assessments conducted by the SNP, the MOC should include a description of that alignment, consistent with the standards in MOC 2, Element B of Chapter 5, § 20.2.2.

We believe the current factors outlined in MOC 2, Element B allows SNPs the flexibility to align a MOC-approved HRAT with other assessment tools (as noted above), and is consistent with the intent of the changes being finalized here in § 422.101(f)(1)(i). Current guidance will be the basis for how CMS will implement and enforce § 422.101(f)(1)(i) to ensure that SNPs incorporate and address the results from the initial assessment and annual reassessment conducted for each individual enrolled in the individual's individualized care plan.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(1)(i) as proposed without modification.

4. SNP Fulfillment of the Previous Year's MOC Goals

We also proposed to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the

previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C-SNPs. We proposed new regulation text at § 422.101(f)(3)(ii) to provide that, as part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care and plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals. Under our proposal, if the SNP MOC did not fulfill the previous MOC's goals, the plan must indicate in its MOC submission how it will achieve or revise those goals for the plan's next MOC. We also proposed to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs to submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3); our proposed paragraph (f)(3)(i) contains the same language as current § 422.101(f)(2)(vi).

We also proposed at paragraph (f)(3)(ii)(A) through (C) specific provisions regarding how NCQA would evaluate the MOC in terms of achievement of goals from the prior MOC. We explained how we intended that NCQA would determine whether each SNP, as part of NCQA's process for evaluation and approval of MOCs, provided adequate information to perform the evaluation required by § 422.101(f)(3)(ii) as well as whether the SNP met goals from the previous MOC submission. After stating that it is implicit in the evaluation of the MOC and the requirement for the SNP to submit relevant information that the information submitted by the SNP must be adequate for NCQA to use to evaluate the MOC, we solicited comment whether more explicit requirements on this point should be part of the regulation text.

We received the following comments on the proposal regarding evaluation of outlining and fulfillment of the MOC's goals and our responses follow:

Comment: CMS received several suggestions related to providing information for evaluation whether the SNP achieved the goals from the prior MOC. One commenter proposed CMS look to the Healthcare Effectiveness Data and Information Set (HEDIS) reporting and measures for direction. Another commenter suggested that CMS evaluate plan performance

monitoring and evaluation metrics included in the MOC, and not goals included in the Individual Care Plan.

Response: We appreciate these suggestions as to the type and scope of information that should be used to evaluate whether a SNP has fulfilled the goals of its prior MOC. We clarify that it is the goals of the MOC (and whether those goals have been met) and not the goals of the ICP that are to be evaluated by NCQA under § 422.101(f)(3)(ii) as proposed and finalized.

We explained in the proposed rule that proposed § 422.101(f)(3)(ii) would align with our current guidance on the MOC submission and review process regarding SNP fulfillment of goals and summarized the current review process. (85 FR 9016) This includes the type of information submitted by SNPs and used by NCQA in evaluating whether the goals of a prior MOC have been fulfilled. Currently, all SNPs are required to identify and clearly define measurable goals and health outcomes as part of their model of care under MOC 4, Element B: Measurable Goals and Health Outcomes for the MOC, as addressed in Chapter 5 of the MMCM. It is critical for all SNPs to use the results of the quality performance indicators and measures to support ongoing improvement of the MOC, and all SNPs should continuously assess and evaluate plan quality outcomes. This is reflected in current guidance in Chapter 5, § 20.2.2 of the Medicare Managed Care Manual. MOC 4, Element B currently contains the following subfactors:

- Identify and define the measurable goals and health outcomes used to improve the health care needs of SNP beneficiaries.
- Identify specific beneficiary health outcome measures used to measure overall SNP population health outcomes at the plan level.
- Describe how the SNP establishes methods to assess and track the MOC's impact on SNP beneficiaries' health outcomes.
- Describe the processes and procedures the SNP will use to determine if health outcome goals are met.
- Explain the steps the SNP will take if goals are not met in the expected timeframe.

The measures identified in the MOC as part of addressing these subfactors are the measures that should be used in evaluating whether the goals of the prior MOC have been fulfilled. Current CMS guidance permits the SNP to identify and describe the measures and data used by the SNP and does not require specific quality measures, such as HEDIS, be used. SNPs may use data and quality performance that CMS measures for the Star Ratings program or through the HEDIS surveys (or other surveys and required quality performance data) but are not limited to those measures and data sources. Subfactors 3 and 4 of Element B provide for descriptions of how the SNP assesses and tracks the impact of the MOC and determines if health outcome goals are met. As proposed and finalized, paragraph (f)(3)(ii)(A) does not list specific types of data or information but requires submission of relevant information pertaining to the MOC's goals and whether those goals were fulfilled. For example, a SNP may submit plan-level health or clinical goals such as controlling diabetes or improving mental health screening access, and provide data showing progress towards these goals. This means that the type and scope of data required are tied to what the MOC's goals are and how the previous MOC addressed MOC 4, Element B. At a minimum, the data and measures described in the previous MOC should be submitted under § 422.101(f)(3)(ii)(A) for determining whether the MOC's goals have been fulfilled but other data may be relevant and pertinent. We expect SNPs to make reasonable determinations about what other data could be submitted as relevant and pertinent for the NCQA evaluation that is required under § 422.101(f)(3)(ii).

For SNPs submitting their initial MOC, NCQA will evaluate the information under MOC 4 Element B as whether the SNP has set clearly definable and measurable goals and health outcomes in the MOC for the upcoming MOC period of performance. For the following submission year, the SNP MOC will be evaluated on whether the measurable goals and health outcomes set in the initial MOC were achieved. We proposed specific regulation text at § 422.101(f)(3)(ii)(B) that plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval and are finalizing that

provision. This new regulation is consistent with our existing regulation and we intend that similar standards will be used going forward as those that are used now regarding the amount of information required from SNPs.

Comment: CMS received several comments expressing concern regarding the incorporation of MOC performance information and data from the previous MOC into the next submission. Commenters noted that plans would need to have complete information on the achievement of goals from the previous year before submission of the next year's MOC in order to meet the new requirement 42 CFR 422.101(f)(3)(ii), and that this short timeframe may prevent plans from being able to provide a complete representation of their performance from the previous year. Others sought further clarification regarding how plans should operationalize the regulation or specific metrics to be evaluated by NCQA.

Response: While we understand the commenters' concern about sufficient information being available each year about the previous year's MOC and performance, we believe that SNPs and NCQA can meet the requirements of the regulation. For SNPs submitting a MOC renewal after one year (because an annual review and approval is necessary), preliminary data from the immediately prior year can provide evidence to the level of fulfillment of the previous MOC's goals. For many I-SNPs and D-SNPs, they will be able to share findings from multiple years of data as part of this requirement because their MOCs will not necessarily need to be reviewed and approved on an annual basis. C-SNPs, which must submit annually under section 1859(f)(5)(B)(iv) of the Act, will be able to select preliminary findings each year from measures that provide evidence of progress on the MOC's goals. Further, for goals that are tied to building on prior performance or making incremental progress in the same or similar area each year, information about performance in more than one prior year may be relevant and pertinent to show how the SNP is fulfilling the MOC's goals. Under MOC 4, Element B of the MOC, SNPs must currently provide a description of the processes and procedures the plan will use to determine if health outcome goals are met. By sharing the findings from these processes, SNPs

can outline achievable steps toward long term goals so that small steps using limited data year to year can be evaluated. Therefore, we believe that SNPs can effectively demonstrate progress to meet the requirements of § 422.101(f)(3)(ii).

As proposed and finalized, § 422.101(f)(3)(ii) requires, as part of the evaluation and approval of the SNP model of care, that NCQA evaluate whether goals were fulfilled from the previous model of care. To serve this purpose, the regulation also requires that:

• Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

• Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

• If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

In each MOC submission and evaluation of the MOC, the SNP must be able to demonstrate that it is continuing to work towards achieving the MOC goals even if the SNP requires additional time or metrics to evaluate the progress. Each MOC should reflect modification of the SNP's strategies to meet the goals of the MOC as needed. Again, under MOC 4 Element B, SNPs are currently submitting health outcome measures used to measure overall SNP population health outcomes at the plan level. SNPs may submit final or preliminary findings from these measures in order to provide evidence of progress as part of each MOC submission.

Comment: Several commenters questioned the applicability of the proposed regulation to D-SNPs and stated that dual eligible enrollees experience changes in eligibility based on their Medicaid status, which the commenters stated impacts the plan's ability to implement and operationalize the MOC.

Response: First, we believe that the process for setting health outcome goals and choosing a set of measures to determine progress permits all SNPs, including D-SNPs, to select

measures that make sense for the population that the plan serves in so far as those measures speak to benchmarks, specific time frames, and how achieving those goals will be determined. A SNP that believes it suffers from disproportionate rates of disenrollment can seek to align outcome measures in a way that recognizes these perceived challenges; however, any measures that the plan selects must be approved by NCQA as part of the MOC approval process. Second, we also believe that the extension of the provision in this rule requiring fulfillment of the previous MOC's goals is consistent with current MOC approval requirements as outlined in Chapter 5, section 20.2.2 (Model of Care Scoring Criteria), as applied currently to all MOC types. The goal of performance improvement and quality measurement is to improve the SNP's ability to deliver high-quality health care services and benefits to its SNP enrollees; our commitment to this is reflected in how it is explicitly stated in section 20.2.2 under MOC 4: MOC Quality Measurement and Performance Improvement, Element B: Measurable Goals and Health Outcomes for the MOC. This goal may be achieved as a result of increased organizational effectiveness and efficiency through incorporation of quality measurement and performance improvement concepts that drive organizational change. The leadership, managers and governing body of a SNP must have a comprehensive quality improvement program in place to measure its current level of performance and determine if organizational systems and processes must be modified, based on performance results.

In addition, section 20.2.2 of Chapter 5 of the Medicare Managed Care Manual provides additional information for plans to identify and clearly define measurable goals and health outcomes for the MOC in listing the five subfactors for Element B of MOC 4. Under factor 1, the SNP's description of measurable goals must include benchmarks, specific time frames, and how achieving goals will be determined. For factor 2, the SNP must include the specific data sources it will use for measurement for the stated health outcome measures. SNPs have flexibility in setting health outcome goals, particularly flexibility to align those goals with the population being served by the plan, but such measures must be approved by NCQA in its review of the

MOC. The rule we are finalizing at § § 422.101(f)(3)(ii) maintains the current level of flexibility for different SNP types in setting goals and the measures and data used to determine if the goals are met. By allowing such flexibilities, the regulation permits SNPs to take into account unique challenges facing their plan (such as potential changes in enrollment due to changes in eligibility for enrollees) and to set goals that allow SNPs to measure progress against these challenges.

For factor 2, the SNP must identify in the MOC the specific data sources it will use for measurement for the stated health outcome measures. We believe that the process for setting health outcome goals and choosing a set of measures to determine progress permits D-SNPs, and all SNPs, to select measures that makes sense for the population of beneficiaries that the plan serves in so far as those measures speak to benchmarks, specific time frames, and how achieving goals will be determined. The regulation we are finalizing at § 422.101(f)(3)(ii) maintains the level of flexibility for different SNP types as it is currently constructed through NCQA's MOC approval process. By allowing such flexibilities, plans can take into account unique challenges facing their plan and to set goals that allow SNPs to measure progress against these challenges.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(3)(ii) as proposed without modification.

5. Establishing a Minimum Benchmark for Each Element of the SNP Model of Care

Finally, we proposed a new regulation at § 422.101(f)(3)(iii) imposing the requirement that benchmarks for each MOC element set by CMS must be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C-SNP model of care and that the MOC can only be approved if each element meets a minimum benchmark. We proposed to implement this requirement and a minimum 50% benchmark for all SNP models of care because medically complex conditions are found in enrollees across all SNP types and implementation of the benchmark requirement only for C-SNPs would be operationally challenging for MA organizations that operate more than one

SNP. In the proposed rule, we stated that each SNP model of care would be evaluated based on a minimum benchmark for each of the four elements and how that was consistent with our current policy. Currently, each subfactor of a MOC element is valued at 0-4 points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60, which is then converted to percentage scores based on the number of total points received. We proposed that each element of the MOC must meet a minimum benchmark of 50 percent of total points as allotted, and a plan's MOC would only be approved if each element of the model of care meets the applicable minimum benchmark.

We received the following comments and our responses follow:

Comment: CMS received several comments that, while receptive to the establishment of the minimum benchmark as proposed, were concerned about the timing of the implementation of the rule. Commenters sought implementation to begin in Contract Year 2022.

Response: We are finalizing the changes to § 422.101(f) as being applicable for contract year 2023 and subsequent years. While this final rule will have an earlier effective date, making these provisions applicable for the period beginning January 1, 2023 provides time for MA organizations to plan and time for NCQA to implement these new standards for use in evaluating MOCs developed and submitted for 2023. Plans that are required to submit MOCs for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for the full implementation and enforcement of this final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

Comment: A number of commenters asked for additional clarity regarding how CMS will implement the scoring of each MOC sub-element.

Response: First, we clarify that NCQA evaluates and scores the MOCs, as part of the NCQA approval requirement that has been in place since 2012 and that will be codified at § 422.101(f)(3) under this final rule. Second, we intend that scoring using the 50 percent benchmarks will be consistent with how MOCs are evaluated and scored now with the addition that the MOC submitted by the SNP must score at least 50% on each element; the scope, content and number of elements and the points available for each element remain the same as outlined in Chapter 5 of the Medicare Managed Care Manual, section 20.2.2.

Currently, the MOC narrative in Chapter 5 addresses four overarching categories: (1) Description of the SNP Population, (2) Care Coordination, (3) SNP Provider Network, and (4) MOC Quality Measurement & Performance Improvement. Each of the four categories is then comprised of a set of required elements, such as Element B: Subpopulation—Most Vulnerable Beneficiaries under the MOC 1 category. These elements and their various factors are reviewed and scored by NCQA and contribute to the overall score for that element. All total, there are 15 elements among the 4 MOC categories. A full list of categories, elements, and factors, as well as additional guidance pertaining to MOC submission requirements and structure, can be found in Chapter 5 of the MMCM. As we explained in the proposed rule, there are a total of 60 points available, across all categories and elements. Each element is scored by NCQA on a range of 0 to 4. To meet the new standard at § 422.101(f)(3)(iii), each MOC must earn at least 2 points for each element.

As proposed and finalized, § 422.101(f)(3)(iii) does not alter the current characteristics or the number of categories, elements, and factors and the mandatory benchmarks will be applied at the element level. For example, the category MOC 2: Care Coordination is made up of five elements:

- Element A: SNP Staff Structure;

- Element B: Health Risk Assessment Tool (HRAT);
- Element C: Individualized Care Plan (ICP);
- Element D: Interdisciplinary Care Team (ICT); and
- Element E: Care Transition Protocols.

A SNP will need to meet a minimum benchmark score of 50 percent for each of Elements A-E. Failing to meet the minimum score in any one element would result in disapproval of the MOC by NCQA during the first round of evaluation. The current process and procedures for the evaluation is not changing under this final rule, so the SNP would be able to resubmit a revised MOC during the cure period after having an opportunity to address the failures identified by NQCA and to revise how the MOC addresses the applicable element(s).

Starting with the MOC for contract year 2023, each SNP will need to meet a minimum benchmark score of 50 percent for each element, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark. CMS and NCQA will provide an overview of any category and/or element deficiencies in our correspondence to plans at the completion of NCQA's MOC evaluation. In addition, each SNP MOC will need to meet an overall score in order to meet NCQA approval, as is the case now.

Comment: CMS received one comment concerned that the introduction of this new scoring process at the element level would potentially derail an otherwise worthy MOC submission.

Response: We believe the final rule is largely consistent with existing regulations and guidance regarding review of SNP MOC standards as plans already receive scores at the element level, though under our current policy approval is based only on the aggregate score.. However, use of minimum benchmarks for each element serves important policy goals by ensuring that each MOC is minimally compliant and that each MOC addresses all of the elements. We also have concerns that the current system potentially allows a MOC to pass while containing a significant deficiency in a specific element. We believe continued guidance and training by CMS

and NCQA will mitigate disruption that may stem from the changes associated with the new scoring process under § 422.101(f)(3)(iii).

As we noted in the proposed rule, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at MOC score data for contract year 2020, our proposed element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. Meaning 20 of the 273 MOCs in 2020 would have been required to resubmit during the cure period of the approval process. For comparison, for contract year 2020, under our current aggregate scoring system, seven plans were required to submit revised MOCs based on the current scoring system and an additional seven plans decided to withdraw their MOCs before the revision process, for a total of 14 MOCs. CMS intends to work with NCQA to ensure that the transition for SNPs to using the new scoring benchmarks for each element is as seamless as possible. Further, the cure period will provide an opportunity to make revisions to address deficiencies identified by NCQA for SNPs that must submit their MOCs for review and approval by NCQA for 2023.

Comment: A commenter expressed concerns that the amended scoring process would be particularly problematic for D-SNPs that enroll beneficiaries with significant and complex medical and social needs.

Response: We believe the MOC review and approval processes are structured to provide a uniform apparatus that already takes into account differences among SNP types and the populations that they serve. As a quality improvement tool, the MOC acts as an important roadmap for ensuring that the unique needs of SNP enrollees are addressed and is a fundamental component of SNP quality improvement. NCQA uses a review process that scores a MOC based on how well a plan has addressed process details and narrative descriptions. Each MOC renewal is an opportunity for a SNP to plan for, lay out, and implement improvements to its processes for each specific element and factor. Even when the MOC guidelines focus on quality improvement and enrollee health outcomes, the MOC review is centered on the SNP's processes and

procedures used to determine if those health outcome goals are met. Under the MOC rubric, CMS does not intend for SNPs to meet specific metric thresholds denoting quality. For example, under MOC, Element B, factor 4, the MOC must describe how it determines if the goals described in factor 1 are met rather than address performance on a specific metric set by CMS. Regardless of SNP type, NCQA applies the review standards uniformly across each MOC submission under this regulation.

Comment: A commenter noted concern that the MOC benchmark was duplicative of the reporting and tracking of plan performance under the Star Rating system.

Response: The MOC requirement is distinct from the goals and purpose of the Star Ratings system so even though there may be some overlap in MA organization and SNP processes in order to successfully implement the MOC and achieve high Star Ratings, we do not believe that these are duplicative or that one should be eliminated in favor of the other.

Section 1859(f)(5)(A)(i) of the Act requires that all SNPs be approved by NCQA based on standards developed by the Secretary; this requirement was added by section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110-275) and became effective with the 2012 contract year. As provided in §§ 422.4(a)(1)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC. Therefore, all SNPs must submit their MOCs to CMS for NCQA evaluation, and an MA organization must develop separate MOCs to meet the needs of the targeted population for each SNP type it offers. NCQA, based on guidance from CMS, has applied scoring standards applicable to all SNP types. The MOC is a forward-looking tool used by SNPs to design processes to perform and improve their performance over a set time period. The Star Ratings system, on the other hand, is used to measure and provide comparative information about the performance of MA organizations on defined measures. Under sections 1853(o) and 1854(b) of the Act, Star Ratings are used in determining payment and beneficiary rebates for MA plans; CMS has adopted provisions, at §§ 422.504(a)(17) and 423.505(a)(26), to use historical,

sustained poor performance on the Star Ratings to evaluate compliance with MA and Part D program requirements and, thus, whether an MA contract should be terminated. In this way, the Star Ratings are retrospective and provide information about past performance, not the MA organization's intentions or plans for improvement and to address enrollee needs in the coming year. Even if past performance can sometimes predict future performance, the Star Ratings program is not the duplicative of a quality improvement program like the MOC. There are other differences between the Star Ratings program and the MOC review and approval process, but these differences in purpose are fundamental and sufficient to conclude that it is appropriate to use a minimum benchmark for approval of all SNP MOCs. Therefore, we are finalizing § 422.101(f)(3)(iii) as proposed to require use of a 50 percent minimum benchmark for each MOC element.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing amendments to § 422.101(f)(1) introductory text, (f)(1)(i), (f)(1)(iii), and (f)(2) introductory text and adding § 422.101(f)(1)(iv) and (f)(3). These provisions are finalized substantially as proposed with a modification in paragraph (f)(1)(iv) to set standards for the required face-to-face encounter.

B. Coverage Gap Discount Program Updates (§§ 423.100 and 423.2305)

We proposed to amend our regulations at §§ 423.100 (definition of applicable drug) and 423.2305 (determination of coverage gap discount) to reflect changes to the relevant statutory provisions made by the BBA of 2018. Sections 53113 and 53116 of the BBA of 2018 amended section 1860D-14A of the Act to (a) increase the coverage gap discount for applicable drugs from 50 to 70 percent of the negotiated price beginning in plan year 2019, and (b) revise the definition of an applicable drug to include biosimilar biological products, also beginning in plan year 2019.

Specifically, section 53116 of the BBA of 2018 revised the definition of "discounted price," meaning the price provided to the beneficiary, in section 1860D-14A(g)(4)(A) of the Act

to mean, for a plan year after 2018, 30 percent of the negotiated price. This means that the coverage gap discount is 70 percent, rather than 50 percent. To make our regulations consistent with this change, we proposed to amend the definition of "applicable discount" in § 423.2305 to provide that, with respect to a plan year after plan year 2018, the applicable discount is 70 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Section 53113 of the BBA of 2018 amended section 1860D-14A(g)(2)(A) of the Act to specify that biological products licensed under subsection (k) of section 351 of the Public Health Service Act (that is, biosimilar and interchangeable biological products) are excluded from the coverage gap discount program only with respect to plan years prior to 2019. Accordingly, CMS has treated biosimilar biological products as applicable drugs under the Discount Program since 2019. Therefore, we proposed to revise the definition of applicable drug at § 423.100 to specify that such biological products are excluded only for plan years prior to 2019[6].

We received four comments on our proposal. The two comments that were within the scope of the rule were supportive of the proposed changes. Therefore, we are finalizing the regulatory change as proposed to amend the definition of "applicable discount" in § 423.2305 to increase the applicable discount from 50 to 70 percent of the negotiated price beginning in 2019, and to revise the definition of applicable drug at § 423.100 such that biosimilar biological products are excluded only for plan years before 2019. As previously noted, these changes are being made to update the regulations to reflect statutory and operational changes that became effective in 2019.

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[6] Unless our policy specifically distinguishes biosimilar biological products from interchangeable biological products, we use the term "biosimilar biological product(s)" in this preamble to reference biosimilar or interchangeable (when such products become available) biological products.

C. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts (§ 423.286)

Section 3308 of the Affordable Care Act amended section 1860D-13(a) of the Act and established an income-related monthly adjustment amount for Medicare Part D (hereinafter referred to as Part D-IRMAA) for beneficiaries whose modified adjusted gross income (MAGI) exceeds the same income threshold amount tiers established under section 1839(i) of the Act with respect to the Medicare Part B income-related monthly adjustment amount (Part B-IRMAA). The Part D-IRMAA is an amount that a beneficiary pays in addition to the monthly plan premium for Medicare prescription drug coverage under the Part D plan in which the beneficiary is enrolled when the beneficiary's MAGI is above the specified threshold.

The Part D-IRMAA income tiers mirror those established for the Part B-IRMAA. As specified in section 1839(i) of the Act, when the Part B-IRMAA went into effect in 2007, individuals and joint tax filers enrolled in Medicare Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, were assessed the Part B-IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, each dollar amount within the income threshold tiers shall be adjusted annually based on the Consumer Price Index (CPI). As a result of the annual adjustment, for calendar year 2010, the income threshold amounts had increased to reflect four income threshold amount tiers for individuals and joint tax filers whose modified adjusted gross income exceeded $85,000 and $170,000, respectively. (We note that section 3402 of the Affordable Care Act froze the income thresholds for 2011 through 2019 at the level established for 2010.)

Consistent with section 3308 of the Affordable Care Act, the Part D-IRMAA is calculated using the Part D national base beneficiary premium (BBP) and the applicable premium percentage (P) as follows: BBP x [(P - 25.5 percent)/25.5 percent]. The premium

percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the Affordable Care Act required CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D-IRMAA no later than September 15 of each year, starting in 2010. Also, effective in 2010, CMS must provide SSA no later than October 15 of each year, with: (1) the modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D-IRMAA in accordance with section 1839 of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out Part D-IRMAA.

To determine a beneficiary's IRMAA, SSA considers the beneficiary's MAGI, together with their tax filing status, to determine the percentage of the: (1) unsubsidized Medicare Part B premium the beneficiary must pay; and (2) cost of basic Medicare prescription drug coverage that the beneficiary must pay.

Since the implementation of the Part D-IRMAA in 2011, subsequent revisions to the statute have modified the associated income tiers used in IRMAA calculations:

- Section 402 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, revised the income thresholds for the Part B- and Part D-IRMAA income groups such that beneficiaries with incomes greater than $85,000 but not more than $107,000 were required to pay 35 percent of Part B and Part D program costs; beneficiaries with incomes greater than $107,000 but not more than $133,500 would pay 50 percent of Part B and Part D program costs; beneficiaries with incomes greater than $133,500 but not more than $160,000 would pay 65 percent of Part B and Part D program costs; while beneficiaries with incomes greater than $160,000 were required to pay 80 percent of Part B and Part D program costs.
- Section 53114 of the Bipartisan Budget Agreement (BBA) of 2018 revised the income thresholds again such that, beginning in 2019, beneficiaries with incomes greater than $500,000

($750,000 for joint tax filers) are required to pay 85 percent of program costs (an increase from 80 percent).

We proposed to revise § 423.286(d)(4)(ii) for consistency with the changes made by section 53114 of the BBA of 2018 and to make other technical changes to ensure that the calculations used in the methodology for updating Part D-IRMAA are described correctly. We proposed to remove the language "the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent and the base beneficiary premium as determined under paragraph (c) of this section" and replace it with "the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR § 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage-25.5)/ 25.5)."

We received no comments on this proposal and are finalizing the proposed revisions to § 423.286(d)(4)(ii) without modification. Although we are finalizing this provision as applicable 60 days after publication, it codifies current policies so we anticipate that there will be no change in operations or administration of the MA and Part D programs and encourage MA organizations and Part D sponsors to take this final rule into account immediately. We note that the revisions to this provision that we are finalizing in this final rule simply codify the Part D-IMRAA calculation that is currently used by SSA.

III. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

A. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 2004 of the SUPPORT Act requires that all Part D sponsors must have established DMPs no later than January 1, 2022. We proposed to amend regulatory language at § 423.153(f) to reflect this requirement. As discussed in the proposed rule preamble, the Overutilization Monitoring System (OMS) criteria used to identify "potential at-risk beneficiaries" (PARBs) (defined in § 423.100) are based on a history of filling opioids from multiple doctors and/or multiple pharmacies. While implementation of DMPs has been optional since codified for 2019, 85.9 percent of Part D contracts in calendar year 2019 and 87.2 percent in calendar year 2020 have established DMPs to address opioid overutilization among their enrollees. Thus, of about 49 million beneficiaries who were enrolled in the Medicare Part D program in 2019, about 48.5 million enrollees (99 percent) are covered under Part D contracts that offer a DMP already. We received the following comments on this proposal and our responses follow:

Comment: CMS received numerous comments that were generally supportive of our proposal to codify the statutory requirement that all Part D plans implement a DMP.

Response: We thank commenters for their support.

Comment: Several commenters expressed concerns that enrollees being treated for pain would be forced, through mandatory DMPs, to see a new doctor or use a new pharmacy and that the proposed regulation would undermine the doctor-patient relationship.

Response: The concerns expressed in some of these comments appeared to reflect a misunderstanding of the requirements in section 2004 of the SUPPORT Act. Although section 2004 mandates the establishment of DMPs for all Part D sponsors beginning January 1, 2022, section 2004 did not expand DMPs' scope. Thus, it is not the case that a "mandatory" DMP

would now require all Part D beneficiaries taking opioids to be subject to coverage limitations or quantity limits. Rather, the statute and the regulations we are finalizing in this rule will now require the few Part D sponsors who have not already established a DMP to do so. DMPs identify a subset of opioid users in the Part D program who may be at the highest risk of an adverse health event, for example, due to uncoordinated care. As mentioned in the proposed rule, CMS' internal analysis estimated that only 158 additional PARBs will be identified per year by applying the current minimum OMS criteria across all Part D contracts that do not already have DMPs in place. CMS expects that only a few of these additional beneficiaries will be subject to a coverage limitation after case management with their opioid prescribers.

CMS does not agree that DMP activities undermine the doctor-patient relationship. In fact, the goal of case management under a DMP is for Part D sponsors to assist prescribers in coordinating care for PARBs to ensure their opioid use is appropriate and medically necessary. The case management process increases safety and accountability within the doctor-patient relationship, as prescribers may or may not be aware that there are other prescribers of opioids or benzodiazepines for their patients. Any potential coverage limitation under a DMP is put in place only after the plan conducts case management, solicits the views of the enrollee's prescriber(s), and provides advance written notice to the enrollee. If a Part D sponsor implements a prescriber and/or a pharmacy limitation, the affected beneficiary is provided opportunities to select their preferred pharmacy and prescriber when they receive an Initial Notice of their PARB status and a Second Notice of their at-risk beneficiary (ARB) status, as described in regulation at § 423.153(f)(5)(ii)(4) and § 423.153(f)(6)(ii)(5). The sponsor is required to consider the beneficiary's preferences consistent with § 423.153(f)(9). These aspects of DMPs safeguard beneficiary's access to coverage of opioids, prescriber and pharmacy choice, and the integrity of the doctor/patient relationship.

Comment: Several commenters requested that PACE organizations be exempt from the requirement to establish a DMP. These commenters noted that drug utilization management

programs, quality assurance measures, and medication therapy management (MTM) program requirements (§ 423.153(a) through (d)) are currently waived for PACE under § 423.458(d). Commenters also stated that the PACE model of care already addresses opioid overutilization through use of a closed provider network; care coordination through primary care providers and the interdisciplinary team; proactive drug utilization review; and in-person health assessments already required for PACE enrollees.

Some of these commenters noted that, while the majority of PACE participants do not reside in an LTC facility, PACE participants are required to meet their state's eligibility criteria for nursing home care and therefore share characteristics with beneficiaries who are exempt from DMPs because they are residents of LTC facilities. They also state that PACE organizations typically contract with a single pharmacy which inherently coordinates access and achieves the goals of a DMP. One commenter noted that many PACE organizations do not have formularies and therefore no Pharmacy and Therapeutic (P&T) committee to develop and carry out DMP policies and procedures.

Response: CMS thanks these commenters for their feedback, but disagrees that PACE organizations should be exempt from the statutory requirement to establish a DMP. While the DMP statute does outline certain exempted beneficiaries, such as individuals with cancer or who reside in a LTC facility, it does not specify or contemplate exemptions based on Part D plan type. CMS notes that MA-PDs that require enrollees to access routine care from contracted and/or employed prescribers through an HMO or integrated care model are similarly required under Part 422 to provide coordinated care, but are not exempt from the DMP requirement. As commenters noted, PACE participants are an especially vulnerable Medicare population, and for those who live in the community, additional monitoring will serve as a valuable safeguard to help prevent misuse of opioids. Depending on the frequency of engagement between the participant and PACE organization, as well as participant preferences, the in-person assessments

required under §§ 460.104 and 460.121 may not always coincide with identification through the OMS, and may present missed opportunities to intervene.

Under the existing regulatory framework where DMPs are voluntary, approximately 40 percent of PACE contracts have reported to CMS that they already have a DMP in place. In 2019, PACE enrollees accounted for 0.03 percent of all Part D enrollees belonging to a plan with a DMP, and 0.07 percent of Part D enrollees identified in OMS as PARBs because they met the minimum OMS criteria. Based on CMS' analysis used in the proposed rule, PACE enrollees account for 0.14 percent of total Part D enrollees identified as PARBs because they meet the criteria for history of opioid overdose (see discussion in this section of this rule), which is proportional to the number of PACE enrollees in Part D (for January 2020, 0.1 percent of all Part D enrollment). In other words, the likelihood of a PACE participant being identified as a PARB, either based on OMS criteria or history of opioid overdose, is at least as high as the likelihood of any Part D enrollee to meet those criteria. Therefore, a PACE participant is as likely as any other Part D enrollee to benefit from case management and should not be deprived of this aspect of the Part D program. As discussed in the proposed rule preamble, Part D sponsors with DMPs infrequently implement coverage limitations after case management. This reflects the goals of case management as a means through which Part D sponsors engage prescribers, gather relevant patient-specific information not available to CMS, such as more recent medical or prescription claims data, and seek to coordinate care tailored to the unique needs of the beneficiary. CMS expects the volume of PARBs identified through minimum OMS criteria in the PACE organizations that have not yet implemented a DMP will continue to be minimal and present a low overall burden for these organizations. As with other Part D plans, such burden includes conducting case management, implementing any needed coverage limitations, and reporting of case management outcomes and coverage limitations back to CMS via OMS. Reporting outcomes of case management provides CMS with valuable information to help track the safe

use of opioids and benzodiazepines in the Part D program and serves as a means to document that case management occurred.

CMS agrees with commenters that a PACE organization, or for that matter, any Part D plan sponsor, that does not have a P&T committee would not be in compliance with existing §423.153(f)(1), which requires approval of DMP policies and procedures by the "applicable P&T committee." As specified in § 423.120(b), only Part D sponsors that use formularies must have a P&T committee, and CMS did not propose to broaden that requirement to apply to Part D sponsors that do not use formularies. For this reason, after consideration of the comments, CMS is amending the language at § 423.153(f)(1) to account for Part D sponsors, including PACE organizations, that do not have their own or a contracted P&T committee (for example, through their PBM) because they do not use a formulary. Such sponsors can comply with this requirement by having written DMP policies and procedures that are approved by the Part D sponsor's medical director and applicable clinical and other staff or contractors, as determined appropriate by the medical director. We have also added cross references to the existing regulations requiring that Part D sponsors have a medical director at § 423.562(a)(5), and for PACE organizations, at § 460.60(b).

Comment: Several commenters stated general concerns or recommendations regarding DMPs. Commenters expressed concerns regarding the misapplication of the CDC Guideline for Prescribing Opioids for Chronic Pain[7] and recommended that CMS direct sponsors towards appropriate disease-specific pain management guidelines. Additional recommendations included facilitating or encouraging providers to refer patients to non-pharmacologic therapies for pain; ensuring provider education about overdose and naloxone prescribing, including evaluation for substance use disorder; ensuring shared decision-making between beneficiaries and prescribers such that access to medically necessary opioids is not impeded; ensuring beneficiaries with a

[7] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

coverage limitation are not forced to use a pharmacy in which the sponsor has a financial interest; and generally ensuring DMP activities are non-punitive or stigmatizing.

Response: CMS appreciates the concerns and recommendations commenters shared regarding case management activities. We note that the recommendations are not inconsistent with the current DMP requirements.

In finalizing the regulatory framework for DMPs (83 FR 16440), CMS made a conscious effort that DMP activities would not be punitive or stigmatizing and would not inappropriately limit access or result in abrupt opioid tapering. This is consistent with the CDC's commentary[8] published in 2019, which advised against the misapplication of the Guideline for Prescribing Opioids for Chronic Pain, including the inflexible application of the Guideline's dosage recommendations and policies that encourage abrupt tapering, sudden discontinuation, or dismissal of the patient from their physician.

CMS agrees that many of the suggestions proposed could be of value in many cases, and encourages sponsors to incorporate them, as appropriate, into their DMP policies and procedures, as well as protect against the unintended consequences identified by the CDC. Finally, CMS notes that beneficiaries are provided opportunities to select their preferred pharmacies and prescribers, if their plan intends to apply a pharmacy or prescriber limitation under the DMP. See § 423.153(f)(5)(ii)(4) and § 423.153(f)(6)(ii)(5).

Comment: A few commenters stated that mandatory DMPs are redundant with existing prescription drug monitoring programs (PDMPs).

Response: CMS disagrees that DMPs are redundant with PDMPs. PDMPs are state-level electronic databases that are used to collect information on all controlled substance prescriptions in a state. While PDMPs, which allow providers to access their patients' prescription history, are one tool to combat the opioid epidemic, PDMPs do not exist in all states, and health plans may not have access to them. Also, while CMS encourages providers to use PDMPs prior to issuing

[8] https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

prescriptions for controlled substances, it is not mandatory for providers to do so in all states.[9] Therefore, CMS believes that DMPs provide additional value for ensuring safe opioid prescribing in the Part D program through the initiation of case management and care coordination activities. Moreover, the CARA statute required CMS to establish a regulatory framework for DMPs.

Comment: Several commenters requested CMS clarify existing guidance with regard to identification of PARBs, criteria for identifying exempt beneficiaries, reporting requirements for ARBs, and notice requirements for exempt beneficiaries. Several commenters provided additional recommendations, including suggestions to expand the list of frequently abused drugs to drugs beyond opioids and benzodiazepines (for example, other central nervous system depressants such as gabapentin) and allowing beneficiaries with existing beneficiary-specific POS edits that were implemented prior to 2019 be integrated into the DMP.

Response: CMS' proposal was to implement the statutory requirement that Part D sponsors establish DMPs as of January 1, 2022. As discussed in section VII.L, CMS also proposed to designate beneficiaries with sickle cell disease as exempted individuals in the regulation for purposes of a Part D sponsor's DMP. CMS did not propose any changes to the other existing requirements, except to solicit comment about case management for PARBs with a history of opioid related-overdose, which is discussed later in this section. CMS will consider revisions to the guidance and OMS criteria as appropriate. CMS also regularly reviews data submitted into OMS and MARx and will update guidance and/or communicate with sponsors if needed.

After consideration of the comments received, CMS is finalizing the proposal to make DMPs mandatory at § 423.153(f) with a modification at § 423.153(f)(1) to accommodate Part D plans, such as PACE organizations, that do not have a P&T committee, as described earlier.

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[9] Centers for Disease Control and Prevention. What States Need to Know about PDMPs. Accessed June 10, 2020 from https://www.cdc.gov/drugoverdose/pdmp/states.html

B. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) and notify the sponsor of such identification, as those individuals must be included as PARBs for prescription drug abuse under their Part D plan's DMP. In line with this requirement, CMS proposed to modify the definition of "potential at-risk beneficiary" at § 423.100 to include a Part D eligible individual who is identified by CMS as having a history of opioid-related overdose, which is also defined in this regulation.

Based on the analyses and rationale described in detail in the proposed rule, CMS proposed to operationalize this definition by: 1) using diagnosis codes that include both prescription and illicit opioid overdoses; 2) using a 12-month lookback period from the end of each OMS reporting quarter for record of opioid-related overdose; and 3) using a 6-month lookback period from the end of each OMS reporting quarter for record of a recent Part D opioid PDE. The number of unique beneficiaries identified under this proposal is approximately 18,268 annually (based on opioid-related overdose claims from July 1, 2017 to June 30, 2018). Under existing rules, which CMS did not propose to change, Part D sponsors with DMPs must conduct case management for each PARB identified by CMS through OMS, which includes sending written information to the beneficiary's prescribers that the beneficiary has been identified as a PARB. In expanding the definition of PARB by adding beneficiaries with a history of opioid overdose, Part D sponsors must conduct the same case management process for this additional group of beneficiaries that they currently conduct for PARBs identified based on their use of multiple opioid prescribers and/or pharmacies. As discussed in the proposed rule, CMS expects that case management for these individuals will involve sponsors communicating with their provider(s), who may or may not already be aware of the beneficiary's overdose history.[10] CMS

[10] Additionally, the beneficiary with an overdose may or may not meet OMS criteria.

also solicited comments on whether the proposal needed any additional features to facilitate the case management process for PARBs with a history of opioid-related overdose.

CMS received numerous comments on this provision, which were largely supportive of the proposal, with several commenters expressing concerns or requesting clarification on various aspects as discussed in this section of this rule.

Comment: A few commenters pointed out that the regulatory text defining potential at-risk beneficiary at § 423.100 was unclear with regard to whether both an overdose diagnosis and an opioid PDE were necessary to meet the new definition of a PARB based on the proposed regulation.

Response: In response to these comments, CMS clarifies that both criteria are required to meet the definition of a PARB with a history of opioid-related overdose. In order to improve overall clarity in this final rule, in lieu of revising the PARB definition at § 423.100 as proposed, we are incorporating the elements of the proposed definition into the clinical guideline regulation as criteria in a new paragraph at § 423.153(f)(16)(ii)(2). That is, the criteria initially proposed in the definition of PARB at § 423.100 have been relocated to the DMP clinical guidelines section of the regulation at § 423.153(f)(16)(ii)(2). CMS has also made some technical changes to the criteria now located at § 423.153(f)(16)(ii)(2) to clarify that a plan can use its own data to identify PARBs. Specifically, instead of referring to "PDE," the criteria will refer to "claim" and the words "has been submitted" are struck from the criteria.

Comment: A few commenters expressed concern with identification of overdose based on diagnosis code, citing anecdotal reports that the codes are unreliable due to being assigned inappropriately or over-diagnosed in beneficiaries taking opioids who present for emergency care for other health conditions.

Response: CMS disagrees and was unable to find evidence to substantiate this claim specific to opioid-related overdose in the published literature. In the event a situation such as this does occur, during the case management process the prescriber will likely review the diagnosis

and determine whether to discuss it with their patient on a case by case basis. Such review and discussion will present an opportunity for the provider to evaluate whether the diagnosis appears to be inaccurate and to communicate this information back to the sponsor's DMP.

Comment: A commenter suggested CMS include both primary and secondary diagnosis codes for opioid-related overdose to avoid under-reporting.

Response: CMS believes the principal diagnosis code is the most reliable means to identify overdoses in order to meet the statutory requirement for the reasons that follow.

According to the ICD-10-CM Official Guidelines for Coding and Reporting,[11] the principal diagnosis code is the condition, after study, to be chiefly responsible for occasioning the admission of a patient to the hospital. The terms principal and primary are used interchangeably to define the diagnosis that is sequenced first on a claim. Other diagnoses, including secondary diagnoses, are conditions that may coexist at the time of admission, or develop subsequently. As such, secondary diagnoses may capture overdoses not directly related to the beneficiary's recent use of opioids that triggered the overdose event. CMS' proposed criteria for identification of a PARB based on history of opioid overdose specifies "recent" overdose so that DMP activities can be the most relevant and impactful. Since secondary diagnoses may be historical, CMS does not believe that they as reliably reflect "recent" opioid-related overdoses as do principal diagnoses.

Taking program size into account, focusing on the principal or primary diagnosis chiefly responsible for the admission or event is most appropriate to capture overdoses related to a beneficiary's recent use of opioids and increase the likelihood that the beneficiary would benefit from case management. Using the same time period, diagnosis codes, PDE, and lookback period criteria described in the proposed rule methodology, CMS evaluated the number of PARBs that would be identified by the proposed definition, both including and excluding secondary diagnoses. Including secondary diagnosis codes for identification of opioid-related overdoses

[11] https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-Coding-Guidelines.pdf

was found to increase the number of PARBs identified by about 40 percent (for a total of 25,566) relative to the number of PARBs identified only on the basis of principal diagnosis (18,268, as described in burden estimates). However, due to the limitations of secondary diagnoses themselves, described earlier, CMS believes the additional PARBs identified solely on the basis of a secondary diagnosis would not necessarily be those with the most relevant history of opioid-related overdose. Therefore, CMS does not believe that the increased program size due to including secondary diagnosis codes for the purpose of identifying PARBs is a cost-effective use of DMP resources, when these resources would be better focused on beneficiaries at highest risk of misuse or abuse.

In evaluating this comment, CMS noticed that the proposed regulatory language in the definition of PARB at § 423.100 was not sufficiently broad to include data sources and methodology discussed in the proposed rule. As mentioned in response to a prior comment, the criteria initially proposed in the definition of PARB at § 423.100 have been relocated to § 423.153(f)(16)(ii)(2). Specifically, in the clinical guideline criteria for identifying PARBs on the basis of history of opioid-related overdose at § 423.153(f)(16)(ii)(2), the words "Medicare fee-for-service" and "code" were stuck from what was in the initially proposed definition at § 423.100. This revised language, which CMS is finalizing, better reflects CMS' intention to use claims, including encounter data, resulting from healthcare visits involving opioid-related overdoses. With this modification, the broader criteria will encompass both inpatient and outpatient locations of care.

Comment: A commenter requested addition of the ICD-10 code Z91.5 for method suicide attempt to capture intentional overdose in the methodology CMS will use to identify PARBs based on history of opioid-related overdose.

Response: CMS disagrees, as the ICD-10 code Z91.5 indicates a history of self-harm, and does not specify self-harm via opioid use. Although the literature CMS cited in the proposed rule preamble does reference history of opioid-related overdose being a risk factor for future

overdoses or suicide-related events, the SUPPORT Act directs CMS to identify beneficiaries with a history of opioid-related overdose. Thus, including the ICD-10 code for history of self-harm would be overly inclusive. Other ICD-10 codes are more specific to identify injury due to opioid-related poisoning or overdose, and are used in the methodology applied by CMS and described in more detail in the February 2020 proposed rule. CMS believes the ICD-10 codes used in this methodology will capture both intentional and unintentional overdoses.

Comment: A commenter pointed out that using Medicare data will not capture overdose history from new Medicare enrollees.

Response: CMS acknowledges this is a limitation to the methodology; however, it is not feasible to gather all non-Medicare claims data for Medicare beneficiaries. We believe using Medicare claims data strikes the right balance to permit inclusion of beneficiaries with a history of opioid-related overdose in DMPs without undue burden.

Comment: A commenter expressed the opinion that for beneficiaries with overdoses due to illicit opioids, coverage limitations on prescription opioids would not likely impact future overdose risk.

Response: CMS disagrees with the commenter's assertion given the criteria CMS has proposed for identifying a PARB based on history of opioid-related overdose. The statute requires that beneficiaries with a history of opioid-related overdose be included as PARBs without specifying that the overdose involve a prescription opioid; therefore, we believe it is appropriate to include beneficiaries with a history of illicit opioid overdose. In the methodology presented in the proposed rule, CMS discussed the fact that in some cases, it is not possible to identify whether an opioid that contributed to overdose was obtained legally or illicitly. CMS also notes that any beneficiaries identified in OMS due to a history of opioid overdose, regardless of whether such overdose was illicit, will have also received an opioid prescription, consistent with the proposed criteria. Thus, there is still a potential role for case management, including conveying the overdose diagnosis to the beneficiary's prescriber(s), who may consider

this information for ongoing opioid prescribing or referral for other health services, with or without the implementation of a coverage limitation for Part D prescription opioids. For example, a prescriber may refer the beneficiary for medication-assisted treatment, if appropriate, based on evaluation of their patient.

Comment: A commenter suggested that CMS' proposal may discourage overdose patients who self-treated with naloxone from seeking follow-up medical care to avoid an overdose diagnosis and potential DMP enrollment.

Response: CMS appreciates the commenter's concerns for these beneficiaries, and recognize the stigma they may face because of such diagnosis. However, the statute requires including these beneficiaries as PARBs, and the commenter's concerns do not obviate the need for CMS, Part D plan sponsors, or health care providers from engaging in rigorous patient safety programs, especially for this vulnerable population. CMS encourages plan sponsors, prescribers, and advocacy organizations to assist in efforts to educate beneficiaries about the risks and benefits of opioid use, as well as their options for opioid use disorder treatment. See section III.D of this final rule for additional information about CMS' efforts, as well as the "Information for Patients" resource provided on the Drug Management Program page of the CMS website.[12]

Comment: A commenter requested clarification if a beneficiary would no longer be considered a PARB once they no longer meet the overdose criteria.

Response: It depends. Once a beneficiary is identified as a PARB based on a history of opioid-related overdose and reported to Part D sponsors, sponsors must review the case and submit responses through the OMS. CMS will update the guidance, including the OMS user guide, to account for scenarios appropriate to PARBs identified based on a history of opioid-related overdose, including where these beneficiaries simultaneously or at a different time meet the definition of a PARB based on the existing OMS criteria, or where the situation changes while the plan is engaged in review/case management.

[12] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

Comment: Many commenters, while supportive of the proposed regulation, asked CMS to clarify expectations for case management, outline expectations for case management outcomes, and provide guidance for management of PARBs identified by a history of opioid-related overdose.

Response: CMS acknowledges these comments about Part D plans conducting case management with prescribers who are treating PARBs with a history of opioid-related overdose. Case management is an integral part of the DMP process. It serves the purpose of engaging in clinical contact with the prescribers of FADs, verifying whether the beneficiary is at risk for abuse or misuse of FADs, and obtaining agreement to a coverage limitation on FADs, if a limitation is deemed necessary. The goal of case management under a DMP is to improve patient safety and care coordination, while protecting beneficiary access to coverage of needed medications.

CMS expects that the overall elements of case management should be similar for all PARBs, regardless of whether identified by existing OMS criteria based on use of multiple opioid prescribers and/or pharmacies or on a history of opioid-related overdose. CMS continues to recognize that every case is unique and that the approach to case management will vary depending on many factors, such as the complexity of the case and the promptness with which prescribers respond to sponsors' outreach. CMS continues to encourage sponsors to use flexibility and clinical discretion depending on prescriber input and patient-related variables. Case management activities should align with desired goals of the DMP, for example, reducing multiple opioid prescribers and/or reducing risk of a subsequent overdose. In estimating the burden for this provision in the proposed rule, CMS estimated that beneficiaries with a history of opioid-related overdose would potentially have a higher rate of coverage limitations imposed by sponsors than beneficiaries meeting minimum or supplemental OMS criteria because a history of

overdose is the most predictive risk factor for another overdose or suicide-related event.[13] However, this is only a pre-implementation estimate and CMS continues to emphasize that the implementation of coverage limitations should be based on individual risk factors and goals identified through case management.

Plan sponsors should continue to refer to CMS guidance on elements that may be incorporated into case management, including prescriber education on opioid overutilization, encouraging prescribers to perform or refer their patients for substance use disorder screening and/or assessment, referral for follow-up treatment with pain specialists or addiction treatment providers, if indicated, and encouraging prescribers to utilize PDMPs to which they have access.

DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. The U.S. Department of Health and Human Services also issues guidance for safe opioid prescribing, including naloxone co-prescribing.[14]

Comment: Many commenters inquired about sponsor flexibility with regard to identification of PARBs based on a sponsor's own claims data, applying the criteria to identify PARBs with a history of opioid-related overdose more frequently than the OMS quarterly reports, or using criteria beyond those proposed by CMS to identify beneficiaries at risk of overdose at the time of their first opioid fill.

Response: CMS appreciates these comments. Just as currently permitted with the minimum OMS criteria, sponsors are permitted to identify PARBs with a history of opioid-related overdose more frequently than the CMS-generated reports through OMS. CMS expects that Part D sponsors identify PARBs consistent with the revised clinical guidelines CMS is finalizing at § 423.153(f)(16)(ii)(2). The clinical guidelines specify a recent (that is, within the past 12 months) claim containing a principal diagnosis indicating opioid overdose and a recent

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[13] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193-1201. doi: 10.1111/add.13774.

[14] https://www.hhs.gov/opioids/prevention/safe-opioid-prescribing/index.html

claim (that is, within the past 6 months) for an opioid medication. Sponsors are required by regulation to submit responses through OMS within 30 days of the most recent OMS report for all CMS-identified or sponsor-identified beneficiaries. Sponsors do not need to wait to receive an OMS report from CMS to initiate case management for sponsor-identified cases and send beneficiary notices, if applicable. Also, as we previously noted, the clinical guidelines for identifying PARBs that we are finalizing in this rule no longer require that history of opioid-related overdose be determined by CMS. This better reflects sponsors' ability to identify PARBs meeting the clinical guidelines using their own data.

Comment: A commenter requested CMS report Part D beneficiaries to sponsors through OMS with overdose diagnoses, but without a subsequent opioid claim, to proactively target these additional beneficiaries who may be at risk. Another commenter stated that beneficiaries with a history of overdose are already being managed outside of DMPs and therefore DMP activities may be duplicative.

Response: CMS does not agree with the request to report beneficiaries with an overdose diagnosis but no subsequent opioid claim. As discussed in detail in the proposed rule preamble (85 FR 9026), it is essential that all Part D plan sponsors, including standalone PDPs, can identify a prescriber with whom to conduct case management.

Without the presence of an opioid claim, Part D DMPs are not implicated. This does not preclude plans from conducting outreach towards beneficiaries with a history of opioid-related overdose who have not received a Part D prescription opioid, if they are able to identify them. A plan may offer services or interventions tailored to these beneficiaries, as the purpose of the DMP is not to supplant other health care activities that may be of benefit to the beneficiary, but rather to promote safe opioid prescribing practices and utilization in the Part D program. However, these beneficiaries should not be included in DMPs unless they meet the clinical guidelines specified in § 423.153(f)(16).

Comment: Some commenters suggested a 6-month, as opposed to a 12-month, lookback

to identify opioid-related overdoses. Commenters suggested this would enable more timely engagement with beneficiaries and align with the Pharmacy Quality Alliance's (PQA) Initial Opioid Prescribing (IOP) measure.

Response: CMS agrees that identifying beneficiaries as soon as possible after their opioid-related overdose is likely to make DMP activities most impactful; however, we disagree with changing the lookback to 6 months for two reasons. First, CMS describes the rationale for the 12-month lookback. Second, CMS describes why it is not relevant to align the lookback with PQA's IOP measure.

Using a 12-month lookback, CMS anticipates that the first report will contain the largest proportion of overdoses occurring greater than 6 months prior to the report being generated. Going forward, however, CMS anticipates that subsequent quarterly reports will reflect a greater proportion of more recent, and thus, more timely, claims and a smaller proportion of earlier claims that were delayed due to processing errors or late submissions.[15] CMS expects that with regular reporting, the majority of PARBs with a history of opioid-related overdose will be identified on a timely basis. As discussed in the proposed rule, 12 months allows CMS to identify the majority of overdoses and appears to reflect the window of time necessary to capture the majority of processed claims or encounters. CMS will evaluate the implementation of the new clinical guidelines to identify PARBs based on history of opioid-related overdose and revise the operational specifications in the future if needed.

The PQA's IOP measure set includes three separate measures. CMS has included one of these measures, IOP-LD (Initial Opioid Prescribing – Long Duration), in Part D sponsors' patient safety reports. The IOP-LD measure does not consider opioid overdoses; rather, it evaluates when there has been no other opioid prescription in the 90-day lookback period prior to the start of an opioid with a long duration of therapy. Because the IOP-LD measure is largely

[15] CMS data indicates that, historically, 90% of FFS claims across all claim types are submitted within 3 months and 90% of MA encounters across all claim types are submitted within 12 months. See: https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf

unrelated to the overdose lookback window, CMS is not persuaded to change the overdose lookback to align with the IOP-LD measure.

Comment: A commenter recommended that CMS exclude beneficiaries with only one opioid prescription during the lookback period from the definition of PARB with a history of opioid overdose. Specifically, the commenter raised concerns about the efficacy of using plan resources to engage emergency department prescribers in case management based on a one-time, short-term opioid prescription.

Response: While CMS understands the commenter's concerns about engaging emergency department prescribers in case management, CMS disagrees with the recommendation to exclude beneficiaries with only one opioid prescription during the lookback period. Given the level of risk to beneficiaries with a history of opioid-related overdose, CMS strongly believes the best policy approach is for plans to attempt to engage their opioid prescribers through case management, even if the prescriber only ordered a single prescription for the beneficiary. CMS does not believe it is appropriate to presume that all such opioid prescribers would decline to engage in case management, given the statutory requirement to include this population in DMPs. Additionally, the DMP regulation at § 423.153(f)(4)(ii) specifies the circumstances under which sponsors may implement a coverage limitation for FADs in the event prescribers are not responsive. Thus, reporting these beneficiaries in OMS as PARBs despite there only being one PDE provides the opportunity for prescriber engagement, but still maintains plan flexibility through the DMP in the event outreach is unsuccessful.

Comment: A commenter cited their concerns with including PARBs with a history of opioid-related overdose in DMPs in light of the Substance Abuse and Mental Health Services Administration's (SAMSHA) 42 CFR part 2 ("part 2") regulations regarding disclosure of substance use disorder (SUD) information. The commenter expressed concern that because Part D sponsors would have to conduct case management with prescribers of all PARBs, which will include beneficiaries with a history of opioid-related overdose, CMS is in effect requiring Part D

sponsors to disclose SUD information about beneficiaries to providers and that such disclosure would be in violation of the part 2 regulations. The commenter requested that CMS provide guidance and/or a safe harbor for sponsors making such disclosures to protect them from any compliance issues.

Response: CMS thanks the commenter for the comment. SAMSHA's part 2 regulations protect the confidentiality of SUD treatment records by restricting the circumstances under which part 2 programs or other lawful holders can disclose such records without the patient's consent. CMS considered these regulations in the development of our February 2020 proposed rule. The requirement to include beneficiaries with a history of opioid-related overdose as PARBs does not require Part D sponsors to disclose SUD information to providers under a DMP; rather, they are communicating to the prescriber as part of case management that the beneficiary has a history of opioid-related overdose. A diagnosis of overdose is not synonymous with SUD or SUD treatment, and CMS will not be reporting SUD treatment records, nor the specific overdose diagnosis code, to Part D plans via the OMS report. We anticipate reporting overdose history in the form of a binary indicator (e.g. "yes/no," "0/1," or other code) on the OMS report if the PARB was identified based on having a history of opioid-related overdose. Additional information, such as the date of overdose, may be provided as well. CMS will provide the updated OMS report file layout and OMS technical guidance in advance of the 2022 contract year. The information CMS will provide in the OMS report will be limited such that 42 C.F.R. part 2 does not apply to the disclosures required under this rule. The restrictions on disclosure and use of SUD information only apply to such information that "would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person." (42 C.F.R. §2.12(a)(1)(i)). Furthermore, under part 2, overdose information that does not reveal the identity of an individual as a SUD patient is not covered by the part 2 rule. The rule does not apply to "[a] diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual

involved does not have a substance use disorder (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs)." (42 C.F.R. §2.12(e)(4)(2)). As detailed in the proposed rule preamble, the diagnosis codes that CMS will use to identify PARBs with a history of opioid-related overdose do not capture the nature of the intent or circumstances of the overdose. CMS is making no assumptions as to the factors that contributed to the overdose, but rather, is deferring to the providers who will be engaged in case management to appropriately evaluate and triage their patients as necessary.

CMS has suggested in the previously cited November 20, 2018 DMP guidance memo that an element of case management could be encouraging prescribers to consider performing or referring their patients for SUD screening and/or assessment. The sponsor should not presume a beneficiary has SUD on the basis of the opioid overdose diagnosis.

Comment: A commenter recommended that beneficiaries with a history of opioid-related overdose be excluded from the criteria for identifying a PARB if there was a subsequent medical claim for opioid treatment program (OTP) services or a PDE for medication-assisted treatment (MAT). The commenter stated that case management through the DMP would not likely offer benefit since presence of either scenario would suggest that an intervention had already been made and risk factors are being addressed.

Response: CMS disagrees that beneficiaries with a claim for OTP services or MAT should be automatically excluded from the criteria for identifying a PARB. Referral to an OTP or initiation of MAT are not the only goals of case management through a DMP. While a claim for OTP services or MAT indicate that an intervention has begun, it does not necessarily mean that the intervention has been successful. CMS believes beneficiaries may still benefit from other elements of the DMP. For example, a coverage limitation on future opioid prescriptions may be beneficial for an individual while in treatment.

In reviewing this comment, CMS realized that the proposed rule had not specified how prescriptions for MAT were treated in the context of requiring an opioid prescription claim in

addition to the opioid-related overdose diagnosis to meet the new PARB criteria. The methodology that CMS used to identify PARBs based on the proposed criteria excluded PDEs for MAT. Only PDEs for non-MAT opioids were included in the analysis and corresponding burden estimates. This is how CMS plans to operationalize the clinical guideline criteria for the purposes of reporting PARBs with a history of opioid-related overdose via OMS. CMS has revised the clinical guidelines at § 423.153(f)(16)(ii)(2) to clarify that prescriptions for MAT will not satisfy the opioid prescription claim criteria for identification of PARBs on the basis of history of opioid-related overdose. Therefore, a beneficiary who has at least one claim with a principal diagnosis indicating opioid overdose, but only has prescription claims for MAT and no other opioids, will not be included as a PARB in the OMS report.

Comment: A few commenters requested that CMS conduct outreach and education to prescribers regarding DMPs and the new criteria for identifying PARBs based on history of opioid-related overdose.

Response: CMS will update educational materials and guidance as appropriate.

Comment: Several commenters requested CMS provide updated model documents to reflect the new criteria for identifying PARBs based on opioid-related overdose history.

Response: Revisions have been made in accordance with the Paperwork Reduction Act (PRA) model notice revision process. Revised notices will be published in the Federal Register for public comment before being finalized and posted on the CMS website.[16]

Comment: Many commenters requested that CMS provide technical specifications, such as OMS report file layout and response codes, well in advance (that is, 6 months) of the expected implementation date so that sponsors would have sufficient time to update internal systems.

Response: CMS appreciates that plans will need time to make operational changes to incorporate this new beneficiary population into their DMPs, and intends to issue guidance and technical specifications to ensure such changes are in place prior to the compliance deadline.

[16] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization

Comment: A commenter recommended that naloxone prescribing should be mandatory.

Response: In the proposed rule, CMS stated that the provider should consider prescribing the beneficiary an opioid-reversal agent if they are newly aware of the beneficiary's history of opioid-related overdose and DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. CMS does not have statutory authority to mandate naloxone prescribing in Part D.

Comment: A commenter suggested that naloxone education be added to model beneficiary notice letters.

Response: CMS will consider this recommendation during the PRA model notice revision process. Revised notices will be published in the Federal Register for public comment before being finalized and posted on the CMS website.[17]

Comment: Some commenters requested clarification that the DMP exemptions still apply to PARBs identified based on history of opioid-related overdose.

Response: Section 1860D-4(c)(5)(C)(v)(I) of the Act specifies that beneficiaries who are not exempted individuals and who have a history of opioid-related overdose must be included as PARBs. Therefore, even if a beneficiary has a history of opioid-related overdose, if the beneficiary also meets the regulatory definition of an exempted beneficiary, as codified at § 423.100, that beneficiary is not to be included in a DMP. Beneficiaries with a known exemption will not be reported via OMS; however, it is possible that it will not be known whether a beneficiary is exempt until case management takes place. Thus, beneficiaries may initially be reported as PARBs but will later be found to be exempt. In this scenario, the beneficiary would no longer be considered a PARB. In response to this comment, CMS is making a technical change to the definition of potential at-risk beneficiary at § 423.100 to clarify that it excludes exempted beneficiaries. This technical change is described in more detail in section VI.M.

After consideration of the comments received, CMS is not finalizing the remaining

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[17] *Ibid.*

changes we had proposed to the definition of "potential at-risk beneficiary" at § 423.100. Rather, we are incorporating those proposed changes into the DMP clinical guidelines at § 423.153(f)(16)(ii)(2). Thus, the clinical guidelines used to identify PARBs, beginning January 1, 2022, will include a Part D eligible individual who is identified as having a history of opioid-related overdose and at least one recent opioid claim, in addition to the existing clinical guidelines based on obtaining frequently abused drugs from multiple prescribers and/or pharmacies. The finalized clinical guidelines for identifying PARBs with history of opioid-related overdose also include modifications to encompass potential data sources and clarify the exclusion of MAT from the opioid prescription component of the guidelines, as discussed earlier in this section.

C. Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amends section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs that are controlled substances when furnishing an in-home health risk assessment. Section 1852(n)(2) requires us to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances.

In order to implement the requirements of Section 1852(n)(1) for MA plans, CMS in its proposed rule (CMS 4190-P) proposed to revise the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2022, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with Section 1852(n)(1), we proposed that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we proposed that MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We proposed that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we did not propose to require MA plans to provide more specific instructions with respect to drug disposal, we did propose that the communication to enrollees would provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also proposed that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*. We noted in our proposed rule that the safe disposal of drugs guidance at this website can be used for all medications not just medications that are controlled substances. We stated in our proposed rule that we believed that plan

communications consistent with the standard on this website would furnish enrollees with sufficient information for proper disposal of controlled substances in their community.

We thank commenters. We received 35 comments on this proposal; we summarize these comments and our responses to the comments follow.

Comment: A commenter expressed concern about the significant operational burden required in performing a health risk assessment in person. This commenter also recommends that CMS allow risk assessments through telehealth such as video conference or a phone call particularly in rural areas where access is an issue.

Response: In-home HRAs are performed in-person where the beneficiary resides and not via telehealth. However, we clarify that this rule is not requiring MA plans to conduct in-home HRAs. In-home HRAs are optional and MA plans may choose to conduct HRAs in this manner. Specifically, the information on the safe disposal of controlled substances is only required to be furnished when an MA plan chooses to conduct an in-home HRA. In this final rule, in consideration of the comments received, we have sought to minimize unnecessary plan burden while also ensuring consistency with the statutory requirement that enrollees who receive an in-home HRA are furnished useful and accessible information on the safe disposal of controlled substances. With the exception of MA SNP plans, all other MA plans are required under § 422.112(b)(4)(i) to make a best effort to conduct an HRA annually and generally do so as part of an enrollee's covered annual wellness visit (see 42 CFR § 410.15), but there is no requirement that the HRA be conducted in-home. We note that MA special needs plans (SNPs), as part of their model of care, are required to conduct annual HRAs for their enrollees (42 CFR § 422.101(f)(1)(i), but are also not required to conduct in-home HRAs.

Comment**:** A commenter asked us to clarify whether the requirement to furnish information about safe drug disposal during an in-home risk assessment applies to risk assessments conducted at other locations where seniors reside, such as senior-living centers, nursing homes or assisted living facilities.

Response: If the enrollee's primary residence is in an institutional setting (such as a nursing home) the enrollee typically will not be responsible for the disposal of unused medications. Therefore, for purposes of this requirement, we would not consider a health risk assessment furnished to an individual who is residing in an institutional setting such as a nursing facility to be an "in-home" health risk assessment, and the MA plan is not required to furnish the enrollee with the guidance on the safe disposal of controlled substances during the HRA as required at § 422.111(j). We have added language to § 422.111(j) clarifying this exception.

Comment: Several commenters questioned how CMS will confirm compliance with these disclosure requirements. The commenter asked CMS to clarify any member material requirements regarding confirming receipt of this information. For example, the commenter questioned whether enrollee attestations would be required. A commenter asked that CMS provide additional clarity about what must be included in the health risk assessment to be compliant with this requirement.

Response: MA plans conducting an in-home HRA must document the visit and their provision of the required disclosure to the enrollee as described at § 422.111(j). However, we are not imposing any additional requirements beyond written documentation that would otherwise be available to CMS upon review or audit that the safe disposal instructions have been met.

Comment: A commenter recommend that CMS explore additional methods to improve take-back programs, such as allowing direct-to-consumer incentives for returning unused opioids. The commenter proposed that rewards and incentives (R&I) could take the form of coupons, gift cards, and electronic deposits to a digital wallet, or other options chosen by the consumer. Another commenter also proposed that CMS explore mechanisms that reverse distributors use to return prescription drugs from healthcare providers and pharmacies back to manufacturers could be leveraged to enable manufacturer-funded incentives that could be shared

with consumers. These commenters stated they believed R&I would help spur individuals to return substantially more unused prescription opioids.

Response: This comment is outside of the scope of this regulation. MA plans may offer R&I programs as specified in our regulations at § 422.134 in section V.D of this final rule.

Comment: A commenter stated that they will be furnishing free kits in a retail pharmacy chain that can be used to dispose of medications in the home. The commenter asked that CMS require plans to inform MA enrollees about this option. Another commenter indicated that they would be selling in-home drug deactivation kits and that CMS should inform MA enrollees of this option. This commenter recommended that CMS require that patient education include information about commercially available in-home disposal products that may be used in disposing of unused medications. Another commenter cited a report indicating that the use of in-home drug deactivation kits is a particularly effective way to facilitate the safe in-home disposal of controlled medications. This commenter also noted that drug deactivation kits would be particularly useful in rural areas where an authorized collector may not be nearby, and that the use of such kits would complement Take Back Day events and give consumers more options.

Response: We recognize that other technologies, such as drug deactivation kits, have been developed and can provide additional options for the safe disposal of unused medications in the home. Accordingly, we are revising the regulation text at § 422.111(j) (5) to add that the written and verbal information on the safe disposal of controlled medications may also include information about the availability of drug deactivation kits for in-home disposal of unused medications. Because these products may not be available to all enrollees and may have varying associated costs for the enrollee, CMS defers to MA organizations to determine whether and how to include such information. As we discuss in more detail in this section of this rule, MA plans have the flexibility to amend the information they furnish on the safe disposal of controlled substances to reflect innovations such as home drug disposal kits that may become available.

Comment**:** Several commenters asked that CMS develop a model document that all MA plans could present to enrollees regarding the safe disposal of controlled substances and identification of community Rx take back sites. Several commenters also recommend that this model information be developed and provided in a format, reading level, and use appropriate visuals to ensure understanding by Medicare beneficiaries. A commenter also asked that CMS consider including in the model general information on drug take-back sites. Another commenter states that with thousands of health plans offering Medicare Advantage products and thousands of health professionals providing HRAs, the need for a common educational document is clear.

Response: We do not believe that developing a model document will allow MA plans the flexibility to tailor their information to the local needs or changes in this rapidly evolving area. For example, the use and expanding availability of drug deactivation kits for in-home use is a relatively new development, and may vary in cost and availability across plans and depending on location. Other new developments or changes in how medications can be safely disposed may become available and we want to preserve the flexibility of MA plans to respond to possible future innovations in drug disposal methods by updating their information without depending on a CMS model document to make those changes. We believe that within the parameters we have established in this regulation, MA plans will have the flexibility to tailor their information to the specific conditions present in the rural, urban or metropolitan community where the enrollee receiving an in-home HRA resides. We expect that as with all written information furnished to MA enrollees that MA plans will use a format, reading level, and use appropriate visuals to aid understanding by Medicare beneficiaries consistent with §422.2267, which we are adopting elsewhere in this rule.

Comment**:** Several commenters expressed concern about the burden of the proposed enrollee disclosure requirement. These commenters specifically mentioned that a verbal explanation of the safe disposal options and also the proposed requirement of identifying local

take back sites are particularly burdensome. This commenter stated it would be impractical to tailor local takeback information for every individual nationwide who receives an in-home HRA. Rather, this commenter urges CMS to adopt a rule that the health professional's reference to the safe disposal website, where local takeback locations can be found, satisfies the requirement to provide such information**.**

Response: The regulations we are finalizing in this final rule will require the verbal instructions to supplement the written guidance on the safe disposal of medications when possible. However, verbal instruction is not required if the enrollee is impaired to a degree where they are unable to receive verbal information. To assist plans in furnishing a verbal communication to enrollees and reduce the burden we are revising the final rule to specify that MA plans will inform enrollees in writing and verbally of two or more drug take back sites that are consistent with the community pattern of access to drug take back sites where the enrollee resides. The verbal instructions should also note that the written instructions contain the DEA web site where the enrollee can identify other community drug take back sites through a search engine where the enrollee can also find current information on the safe disposal of drugs. If the enrollee's spouse or caregiver is the responsible party it would be appropriate to furnish this information (written and verbal) to them when conducting an in-home HRA of an impaired enrollee. We have amended § 422.111(j) to clarify the information that should be shared with the enrollee when a verbal summary of the instructions is possible. We believe providing this information in both written and verbal format is important for the effective transmission of this information to help enrollees appreciate the importance of disposing of unused medications that are controlled substances and that the written document can be used for more details on how to dispose of these unused medications. With respect to identifying local take back sites we recognize that simply referencing a website would be less burdensome. However, as previously noted, in response to these comments, we are modifying our proposal and will require a written and verbal disclosure of at least two drug take back locations that are consistent with the

enrollee's community pattern of access to drug take back sites. Specifically, the identified drug take back sites must be among the drug take back sites that are generally utilized by people residing in the same community as the enrollee receiving the in-home HRA. That is, drug take back sites that are physically located within the shortest travel times. While the identification of two drug take back sites available to the enrollee identifies two choices we encourage plans to identify additional community take back sites.

Comment**:** A commenter asked that rather than furnishing written guidance on the safe disposal of controlled substances the information could be furnished to all MA enrollees in ANOC/EOC documents. Another commenter states that adding this information to the MA plan website would also be less burdensome for members and health plans. One commenter recommends that CMS promote inclusion of safe disposal information within a member's enrollment welcome packet.

Response: We are implementing the statutory requirement at section 1852(n)(1), which requires that specific information on the safe disposal of controlled medications must be provided to MA enrollees who are furnished an in-home HRA. While we acknowledge that this information could be beneficial to other enrollees, given the specific statutory language referencing this subset of enrollees, we are not requiring the inclusion of this information in other MA plan communications, nor are we adding it to the EOC template. While not required, we recognize that information on safe disposal may be useful for all Medicare beneficiaries, and therefore we encourage MA plans to make it available to other plan enrollees, for example by posting it on their website.

Comment**:** Another commenter asks that CMS maintain flexibility for plans to provide beneficiary education and outreach in a way that best suits the needs of individual members while minimizing burden. A commenter asks that CMS allow plans the flexibility to determine what information to provide, including relying on existing, externally validated sources. For example, the U.S. Drug Enforcement Agency (DEA) website at www.deatakeback.com already

hosts an up-to-date, searchable database of locations for safe disposal (located specifically at https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1), and local law enforcement stations routinely collect controlled substances or can direct beneficiaries elsewhere as needed.

Response: The proposed regulation at § 422.111(j)(1)(vi) (which we are renumbering as § 422.111(j)(6)) requires that MA plans include in their written guidance a link to the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html However, we agree that the previously identified DEA website is a useful tool for locating drug take back sites available in specific communities. We will require that MA plans include a link to the DEA website in their written instructions and will require MA plans to provide a verbal summary of the written instruction noting the availability of the DEA website as a source for locating drug take back sites. Therefore, we are amending § 422.111(j)(2) to include the DEA link.

Comment: Several commenters stated that pharmacists are trusted and qualified and should be the source of information to inform enrollees about methods for the safe disposal of medications. The commenters stated that delivering this information to the beneficiary at the point of sale where the beneficiary gets or refills their prescription could be more effective . The commenter believed that at these times, information on safe disposal is more likely to be understood, and the drugs are more likely to be disposed of safely as part of the beneficiary's care routine (for example, expired medications can be disposed of at or near the same location where a new prescription is filled).

Response: As we have previously noted in this preamble, we are implementing the statutory requirement at Section 1855(n), which requires MA plan to furnish information on the safe disposal of controlled substances when conducting an in-home HRA. Elsewhere in this rule

we discuss the statutory requirement for this information to be furnished as part of a Part D MTM program.

Comment: A commenter expressed concern that the various requirements for providing beneficiaries with safe disposal information may result in a beneficiary receiving multiple and varied messages with the adverse effect of beneficiary confusion and/or beneficiary resistance to the safe disposal message. This commenter recommends that CMS and plans make certain such efforts are coordinated with pharmacies to ensure consistent messaging, particularly around treatment alternatives.

Response: As we have previously discussed we are laying out parameters rather than mandating model language with respect to the information that MA plans must furnish to enrollees during an in-home HRA. We believe the parameters we are finalizing at § 422.111(j) give MA plans the flexibility to ensure that their written information remains reasonably consistent with the current drug disposal options available in the communities where their enrollees reside.

We thank the commenters for sharing their concerns and recommendations regarding our proposed implementation of Section 1855(n)(1) in the MA regulations at § 422.111(j). After careful examination of all comments received and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing § 422.111(j) with the following modifications from the proposal. We are renumbering §422.111(j). We recognized the that DEA website is a useful tool for locating drug take back sites available in specific communities. We will require that MA plans include a link to the DEA website in their written guidance and note the availability of the DEA website as part of the verbal instructions to enrollee's when conducting in-home HRAs. Therefore, we are amending §422.111(j)(2) (as renumbered) to include the DEA link at: www.deatakeback.com which includes a page with a searchable database where drug take back sites nearest to a person's home can be identified at the following web link: https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

We are also amending § 422.111(j)(4) to require that the written and verbal instructions identify two or more drug take back sites available in the community where the enrollee resides. We are adding a new provision at § 422.111(j)(5) specifying that as part of its educational information on the safe disposal of controlled medications, the plan may inform enrollees in writing and verbally about the availability of drug disposal kits for the in-home disposal of unused medications. Finally, we are revising § 422.111(j) to clarify that for purposes of this requirement, a health risk assessment is not considered "in home" if the enrollee's primary place of residence, such as a nursing facility, manages the disposal of unused medications.

D. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA-PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D-4(a)(1)(a) of the Act. Section 6102 of the SUPPORT Act amended section 1860D-4(a)(1)(B) of the Act to require that Part D sponsors also must disclose to each enrollee, with respect to the treatment of pain, information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA-PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. Section 6102 also amended section 1860D-4(a)(1)(C) to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period, rather than disclosing the information to each plan enrollee.

To implement section 6102, we proposed to amend our regulations at § 423.128 to require Part D sponsors to send information on opioid risks and alternative treatment information

to all Part D enrollees, with the option to provide such information to a subset of such enrollees, in accordance with section 1860D–4(a)(1)(C), in lieu of providing it to all enrollees.

Paragraph (a) of section 423.128 requires Part D sponsors to disseminate specific plan information to enrollees, under which a sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS. Paragraph (b) lays out information requirements the plan must include for qualified prescription drug coverage offered under the Part D plan. We proposed to revise these requirements by adding paragraph subsection (b)(11) to mandate that Part D sponsors send information about the risks associated with prolonged opioid use, coverage of non-pharmacological therapies, devices, and non-opioid medications, for MA-PDs, coverage under the plan, and for PDPs, coverage under Parts A and B. Additionally, we proposed to add subsection (b)(11)(ii), which gives Part D sponsors the option of sending these resources to a subset of enrollees, in lieu of providing it to every enrollee. In the proposed rule, as shown in Table C1, we suggested 6 different enrollee subsets to whom sponsors could send the required opioid risk and alternate pain treatment coverage information, generally grouped by retrospective review of prescription opioid fills using several different timeframes, with the exception of the subgroup that contains all Part D enrollees. The lookback periods ranged from use of any opioids in last 2 years to greater than 90 days continuous use with a 7-day gap or less in the past year. Table C1 also shows the estimated number of enrollees in each suggested subgroup, as well as the estimated percent of total opioid users in Part D that each subgroup constitutes.

TABLE C1: SUGGESTED SUBSET OPTIONS TO RECEIVE EDUCATION ON OPIOID RISKS AND ALTERNATE TREATMENTS*

Subset	Suggested Subset	Number of Enrollees in this Subset	Percent of Total Part D Opioid Users
1	All Part D Enrollees	46,759,911	N/A
2	Any opioid use in last 2 years	16,134,063	100%
3	Any opioid use in past year	11,027,271	100%
4	7 days continuous opioid use	7,163,615	65%
5	Greater than 30 days continuous opioid use, 7 day or less gap	3,816,731	35%
6	Greater than 90 days continuous opioid use, 7 day or less gap	2,698,064	24%

*All figures based on 2018 PDE data as of 7/6/2019, except subset 2 which is based on 2017 and 2018 PDE data. Beneficiaries were excluded from the opioid use subsets if they were in hospice, in a resident facility, or had a palliative care diagnosis

(07/01/2018 - 12/31/2018). Beneficiaries were also excluded if they had a cancer diagnosis (01/01/2018 - 12/31/2018). No exclusions were applied to the all Part D enrollees figure (subset 1).

We specifically solicited comments from stakeholders on the various suggested subsets of enrollees to whom the required information could be sent, in order to determine if there was any consensus that might inform sponsors' decisions, whether based on our suggested subsets or otherwise.

Comment: Many commenters were supportive of our proposal as an additional means to support efforts to address the national opioid crisis.

Response: We thank these commenters for their support of the proposed provision.

Comment: A few commenters expressed concern about overreach in sending the required information to all Part D enrollees. They highlighted the potentially negative reactions enrollees may have if they receive this information without having record of a previous opioid prescription. Conversely, other commenters believed that it was important for all enrollees to receive the information whether or not they had a record of a prior opioid prescription, noting that successful public health campaigns are not always tailored to specific populations. Other commenters supporting that the information be disclosed to all Part D enrollees noted that some beneficiaries may have paid cash for opioids or used illicit ones, and thus would be missed in any subset based on prescription opioid use. A few commenters believed that plans could focus their efforts on beneficiaries who have received an opioid in the last 7 days, so as to not be over-inclusive with the information disseminated to them. No other commenters suggested a different subset of enrollees to whom the information should be provided.

Response: We appreciate the commenters' feedback. Although some commenters offered their opinion on the enrollee population that might be the best group to receive the information, there was no consensus to inform sponsors' ultimate decisions on to whom to send the information. As we have noted, the statute leaves this decision to the sponsor's discretion.

Comment: Several commenters encouraged CMS to develop a model document for sponsors to use for consistent messaging about the risk of opioid use and coverage of alternative pain treatments.

Response: We do not believe a model document is appropriate or necessary. Both MA-PDs and standalone PDPs should be able to describe the risks of prolonged opioid use without a model document, as they possess the expertise in both the coverage and clinical use of drugs and their associated risks. In addition, Part D sponsors have available to them federal government websites as resources for consistent messaging. For example, the U.S. Department of Health and Human Services website (https://www.hhs.gov/opioids/) contains information about opioid risks and pain management options, and CMS' Pain Management website (https://www.medicare.gov/coverage/pain-management) also contains information about the risks of opioids and pain management.

Moreover, we anticipate that sponsors will require some flexibility when it comes to developing the content for these beneficiary notices, given that they have the discretion to choose a subset of enrollees to whom they will send the notices. Also, coverage of alternative pain treatments will likely vary among plans. Additionally, a plan's beneficiary population can be unique and opioid issues may vary regionally and over time. Thus, the degree of flexibility any model document would require to allow each plan to tailor its message and information to its specific plan population in terms of coverage of the risks of prolonged opioid use and alternate pain treatments would decrease the utility of a model document.

Comment: A commenter suggested that this information could be conveyed to Part D enrollees through the EOC.

Response: We respectfully disagree. While the EOC does contain information about plan coverage of alternate pain treatments, such as coverage of physical therapy services in an MA-PD, it is a very large document containing hundreds of pages of material, which is not the best

method to provide the specific, cohesive, and concise information on opioid alternatives that is required under this provision.

Moreover, given that Section 6102 of the SUPPORT Act provides for specific opioid education to Part D beneficiaries, we do not believe that adding opioid risk and alternative pain treatment coverage to a lengthy technical document would draw sufficient attention to the required information. For this reason, we believe that a separate beneficiary communication is a more effective means of conveying this information. We may consider revising the EOC template in future years so that a plan may include this information; however, our current focus is on implementing the statutory requirement and believe it is best implemented as we proposed.

Comment: Some commenters requested clarification on whether Part D plans are permitted to send the required information electronically without prior consent of the beneficiary, based on requirements they referenced from § 423.128(b), which allowed for electronic delivery of EOCs without prior beneficiary authorization. Specifically, the regulation allowed plans to meet the disclosure and delivery requirements for certain documents by relying on notice of electronic posting and provision of the documents in hard copy when requested, when previously the documents, such as the EOC, had to be provided in hard copy.

Response: As stated under § 423.2267(d)(2)(ii), which we are finalizing as discussed elsewhere in this rule, we will not allow for electronic delivery without prior approval from the beneficiary for this type of material. Part D sponsors may only mail new and current enrollees a notice for electronic access to the EOC, Provider and Pharmacy Directories, and Formulary without beneficiary authorization. Conversely, the separate beneficiary notice on opioid risk and coverage of alternate pain treatment is a new document that will convey important safety information related to a national epidemic, and we want to make sure that beneficiaries will see the information. For this reason, we are not making any exceptions to § 423.2267(d) for this information, and Part D plans must obtain the beneficiary's consent before they may provide this information electronically.

Comment: As we noted earlier in section A, we received many general comments expressing concern that the opioid provisions of the proposed rule would limit access to pain medicine, including opioids.

Response: We are not persuaded that educating beneficiaries about the risks of opioid use and coverage of alternative pain treatments will prevent people who need opioids for treatment of their pain from receiving them. It is commonly accepted that beneficiaries should discuss their health care treatment choices and the potential risks associated with each choice with their health care providers, and that the more education beneficiaries have about their options and the associated risks when they have these conversations, the better able they will be to make the best choice for themselves in consultation with their providers.

After consideration of the comments received, we are finalizing the new requirement at § 423.128(b)(11) to disclose information to enrollees about opioid risks and alternatives without modification except thatthis provision will be applicable beginning on January 1, 2022 rather than January 1, 2021 as initially proposed. However, given the ongoing national opioid epidemic and public health emergency, we strongly encourage Part D sponsors to disclose this information to their enrollees in 2021, if possible. We also encourage sponsors to include information in these notices, as they deem appropriate, to help increase awareness among Part D enrollees about access to medication-assisted treatment (MAT) and naloxone. In this regard, we note that the CMS webpage (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/Index) includes information about the dispensing and administration of MAT medications (if applicable) now covered under the new Opioid Treatment Program (OTP) benefit under Medicare Part B. We also note that in the CY 2020 Call Letter, CMS previously encouraged Part D sponsors to engage in targeted education of enrollees on co-prescribing of naloxone,[18] and that this beneficiary notice may be an ideal avenue to include such information.

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[18] Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, page 204 (April 1, 2019). https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We proposed to amend Part D Medication Therapy Management (MTM) program requirements in § 423.153 to conform with the relevant SUPPORT Act provisions. The SUPPORT Act modifies MTM program requirements for Medicare Part D plans by expanding the population of beneficiaries who are targeted for MTM program enrollment ("targeted beneficiaries") to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries. Section 6064 of the SUPPORT Act amended section 1860D-4(c)(2)(A)(ii) of the Act by adding a new provision requiring that ARBs be targeted for enrollment in the Part D plan's MTM program. We proposed to codify this requirement at § 423.153(d)(2). Section 6103 of the SUPPORT Act amended the MTM program requirements in section 1860D-4(c)(2)(B) of the Act by requiring Part D plans to provide MTM enrollees with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. We proposed to codify this requirement by adding new paragraphs at § 423.153(d)(1)(vii)(E) and (F).

1. ARBs and MTM

Under our proposed revisions to § 423.153(d), ARBs would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: (1) enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and (2) enrollees who are determined to be ARBs under § 423.100.

Under our proposal, Part D sponsors would be required to automatically enroll all ARBs in their MTM programs on an opt-out only basis as required in § 423.153(d)(1)(v). We did not propose to change any existing MTM program requirements for targeted beneficiaries enrolled in a Part D sponsor's MTM program, including service requirements such as annual comprehensive

medication reviews (CMRs) and targeted medication reviews (TMRs). Accordingly, the MTM program requirements would be the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they are targeted for enrollment based upon the existing criteria or because they are ARBs.

As discussed in detail in the February 2020 proposed rule (85 FR 9031), CMS encourages sponsors to design MTM interventions for this new population of targeted beneficiaries to reflect their simultaneous inclusion in the sponsors' DMPs. CMS also encourages sponsors to consult existing clinical guidelines, such as those issued by the Centers for Disease Control and Prevention for Prescribing Opioids for Chronic Pain[19], when developing MTM strategies and materials. CMS solicited input into how sponsors can best coordinate DMPs and MTM programs and effectively perform outreach to offer MTM services. We also solicited feedback on how to leverage MTM services to improve medication use and reduce the risk of adverse events in this population, how to measure the quality of MTM services delivered, and how to increase meaningful engagement of the new target population in MTM. Lastly, we solicited comments on the type of information that we should use to monitor the impact of MTM services on ARBs, who will now be targeted for MTM services.

CMS also sought comment in the proposed rule on how the CMS Standardized Format (CMS-10396; OMB control number 0938-1154) might be modified in order to accommodate the new population of ARBs that will be enrolled in Part D sponsors' MTM programs. Additionally, CMS posted the CMR Standardized Format with rule-related changes in conjunction with the proposed rule. A version reflecting non-rule related revisions was posted in the Federal Register on February 24, 2020 (85 FR 10444) through the Paperwork Reduction Act (PRA) process with a 60-day public comment period. We also solicited feedback on whether using Health Level Seven (HL7®) - enabled CMRs could positively impact the sharing of CMR data with the

[19] Accessible at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

prescriber for an MTM enrollee, and the value of encouraging Part D MTM providers to use FHIR-enabled platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

Comment: CMS received multiple comments expressing concerns about the timing of the proposed requirements to include ARBs in MTM programs and to provide information on safe disposal of controlled substances to beneficiaries enrolled in MTM. Commenters requested that CMS postpone implementation of the requirement to add ARBs to MTM programs until 2022, citing the time involved to develop an effective MTM program that would serve the new population, including the need to coordinate between MTM providers, behavioral health teams, DMPs, and others. They stated that plans will need time to create the systems required for information exchange to facilitate care coordination. One commenter pointed out that resources are currently being consumed by COVID-19 needs.

Response: Recognizing the impact of the COVID-19 public health emergency on plans and other stakeholders, we are modifying the regulation text at § 423.153(d)(1)(vii)(E) and § 423.153(d)(2)(ii) to specify that these changes to MTM programs must be implemented by Part D plan sponsors beginning January 1, 2022, rather than January 1, 2021 as initially proposed. The applicability date for § 423.153(d)(2) is 60 days after the date of publication of this final rule.

Comment: Many commenters opined on the usefulness of targeting ARBs for enrollment in the Part D MTM program. Some commenters believe that these beneficiaries would benefit from MTM interventions that would create additional opportunities to provide counseling and education to a generally underserved population. Other commenters expressed concern that targeting these beneficiaries for MTM would make this vulnerable population believe they are being singled out or stigmatized, or would increase the size of MTM programs. A commenter questioned CMS' authority to propose this requirement, calling our proposal "bureaucratic over-reach." Other commenters stated that providing ARBs with both DMP and MTM services would

be duplicative and potentially confusing; a commenter pointed out that plans often use one vendor to perform DMP-related services and another for MTM which could lead to a lack of coordination between service providers. A few commenters suggested alternative mechanisms to provide services to the ARBs such as enhancing DMPs or making a beneficiary's at risk status another condition to be considered when developing MTM targeted population.

Response: Section 6064 of the SUPPORT Act, as codified at section 1860D-4(c)(2)(A)(ii) of the Act, requires that Part D plan sponsors include ARBs in their MTM programs. As discussed in the proposed rule, the MTM program requirements are the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they are targeted for enrollment based upon the existing criteria or because they are ARBs. In order to provide services for ARBs, plans will need to coordinate services across both their DMP and MTM program without regard for which vendors furnish such services. Part D plan sponsors are ultimately responsible for ensuring that all delegated functions are compliant with CMS requirements. See 42 CFR § 423.505(i)(1). This includes making sure that downstream entities used to provide a plan's DMP and/or MTM program coordinate, as necessary, to ensure that communications with and services furnished to plan enrollees comply with applicable Part D requirements. To the extent that MTM can be provided within a plan's DMP while meeting all MTM service requirements, this approach would be permissible provided it complies with all other applicable Part D requirements. Further, if a plan wishes to target all PARBs for enrollment in its MTM program instead of only targeting ARBs, it is permitted to do so, provided that the plan meets all CMS requirements for both DMPs and MTM services. The criteria specified in the regulation reflect what is required under the Act, and do not preclude plans from electing to offer

MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under § 423.153(d).[20]

Comment: Several commenters asked CMS for more direction in developing MTM programs that will meet the needs of the new cohort of beneficiaries.

Response: CMS typically gives plans the latitude to develop MTM programs that meet their beneficiaries' needs within the framework of the applicable statutory and regulatory requirements. Most Part D plans have gained experience with their ARB population through DMPs and earlier Part D opioid overutilization policy, and we expect plans to draw on this experience when working with their clinical teams, including any downstream entities, in developing clinically appropriate MTM interventions for these individuals. Consistent with section 1860D-4 (c)(2)(E) of the Act, MTM programs must be developed in cooperation with licensed and practicing pharmacists and physicians.

Comment: Multiple commenters expressed concerns that the addition of ARBs to the MTM population could impact the Part D MTM Program Completion Rate for CMR Star Rating measure, and expressed concerns that including the new population of MTM-eligible beneficiaries in the CMR completion rate might adversely affect a plan's overall Star rating. A commenter cited internal data indicating an expected CMR acceptance rate of 23 percent for current MTM-eligible beneficiaries who also meet the DMP criteria for ARBs. Commenters requested that CMS proactively implement safeguards in the scoring of this measure – some commenters suggesting the measure be excluded from Star Ratings and others asking that ARBs

[20] See HPMS memorandum dated April 5, 2019, "CY 2020 Medication Therapy Management Program Guidance and Submission Instructions" at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf

be excluded from the measure – in order to ensure plans with a high population of ARBs are not adversely and unintentionally affected.

Response: CMS appreciates these comments but believes it is premature to assume that ARBs will be less receptive to offers of MTM services than other beneficiaries prior to gaining program experience. Congress enacted a statutory requirement that Part D plans engage with this population through their MTM programs, and CMS expects plans to develop effective engagement strategies based on their beneficiary population and business model.

The MTM CMR completion rate is a Pharmacy Quality Alliance (PQA) endorsed measure. The denominator currently used to derive the measure includes all individuals who met the MTM eligibility criteria; therefore, while the methodology for the measure is outside the scope of our proposal, as currently defined, the measure would include ARBs beginning with the 2022 measurement period. The extent to which any potential change in a plan's rating on this measure may affect its overall Star Rating would also depend on that plan's performance on all other Star Ratings measures. Lastly, CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule (83 FR 16519 through 16589), published in April 2018, for performance periods beginning with 2019; that final rule lays out the methodology for the 2021 Star Ratings and beyond. If the measure steward changes the specifications for the MTM CMR completion rate measure, the process for CMS to update the Star Ratings measures is codified at § 423.184(d).

Comment: A few commenters expressed concerns about the types of reporting requirements that may be included when ARBs are enrolled into MTM programs, and requested that CMS clarify what those requirements will be. A few commenters urged CMS to consider reducing reporting elements in view of the additional beneficiaries that will be added to MTM programs.

Response: We are requiring plans to comply with the requirement to extend MTM to ARBs beginning on January 1, 2022, and therefore this requirement will not impact plan

reporting until the 2022 plan year data, which is collected in early 2023. Part D reporting requirements for the 2021 plan year (CMS-10185; OMB control number: 0938-0992 expires December 31, 2023) have been approved by OMB and are available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.

Comment: A commenter voiced support for conducting CMR sessions via telemedicine.

Response: We appreciate the reminder that the CMR can be provided via telemedicine, which may be preferable in many situations. The regulation at § 423.153(d)(1)(vii)(B)(*1*)(*i*) specifies that the annual CMR must be provided by an interactive, person-to-person, or telehealth consultation.

Comment: A few commenters requested additional information on when a beneficiary may be considered to be "unable to accept the offer to participate" in a CMR. These commenters contend that it may be necessary to conduct outreach to a provider in cases where barriers due to social determinants of health (SDOH) may prevent the beneficiary from accepting the offer of a CMR, while conducting the CMR with the prescriber would allow the member to receive the benefits that go with MTM programs.

Response: As we explained in the proposed rule, the only situation in which CMS would consider a beneficiary to be unable to accept an offer to participate in a CMR is when the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs. The CMS Standardized Format provides instructions for those circumstances. The flexibility to perform the CMR with a prescriber, caregiver or other authorized individual does not apply to situations where the sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address), if there is no evidence of cognitive impairment, or where the beneficiary declines the CMR offer. Further, perceived barriers due to a beneficiary's SDOH does not mean that the beneficiary is unable to participate in a CMR. MTM providers are expected to make sure that they engage the

target population in a manner that these beneficiaries can understand and use, regardless of any language or other barriers that exist. We also want to caution that the failure to provide services to beneficiaries disadvantaged by poverty, language, or other SDOH suggests discriminatory practices, which may be in violation of the Social Security Act or other federal requirements regarding access to services.

Comment: A commenter asked CMS to clarify the definition of an ARB.

Response: An ARB, as defined at § 423.100, means a Part D eligible individual (1) who is: (i) identified using clinical guidelines (also defined in § 423.100); (ii) not an exempted beneficiary; and (iii) determined to be at-risk for misuse or abuse of such frequently abused drugs (FADs) under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) with respect to whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an ARB (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Comment: A commenter asked whether CMS expects to "grandfather" existing ARBs who have an active coverage limitation placed prior to January 1, 2021 that extends into the 2021 plan year, or whether the new MTM requirement would apply only to ARBs who are newly identified after January 1, 2021.

Response: As discussed earlier, under the regulation we are adopting in this final rule, Part D plan sponsors must comply with the requirement to include ARBs in MTM programs by January 1, 2022. Accordingly, all existing ARBs – that is, enrollees with an active limitation under a DMP as of January 1, 2022, although such limitation may have commenced prior to

January 1, 2022 – as well as ARBs identified on or after January 1, 2022, must be targeted for enrollment in MTM.

Comment: CMS received a number of comments on how to improve the Standardized Format including suggestions on the content and format. Most commenters indicated that electronic sharing of completed CMRs to the prescriber's EHR would promote continuity of care. These commenters urged CMS to produce a template that encouraged HL7® - enabled submissions. A commenter asked when a new MTM Standardized Format will be available for use and when MTM providers will be required to start using any newly developed format.

Response: We thank all commenters for their suggestions. Comments received in response to this regulation will be considered when finalizing the Standardized Format along with those received in response to the PRA package for the CMS Standardized Format (CMS-10396; OMB control number 0938-1154) that was published separately from the rule. An additional 30-day notice for CMS-10396 will be published for public comment following publication of this final rule, and a package will be delivered for OMB review. The 30-day notice will address the comments received in response to the rule- and non-rule solicitations, provide additional proposed revisions if applicable to address the comments, and propose a date for when the changes would become effective. The finalized Standardized Format will be released after approval by the OMB.

Comment: A commenter was concerned that the pecuniary interest of the sponsor will be the primary driver for MTM reviews and that it would create an incentive to "say no" to appropriate and safe opioid therapies for hundreds of thousands of pain patients.

Response: It appears that the commenter may be unfamiliar with the use and purpose of Part D MTM programs. The goal of MTM is to improve medication use and therapeutic

outcomes driven by the individual beneficiary clinical needs and does not result in any denials of medications or services.

2. Information on Safe Disposal of Prescription Drugs that are Controlled Substances for MTM Enrollees

Section 6103 of the SUPPORT Act added a new requirement that Part D plans provide beneficiaries enrolled in their MTM programs with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. To implement this new requirement, we proposed that Part D sponsors would be required to provide this information to all beneficiaries enrolled in their MTM programs at least annually, as part of the CMR or through the quarterly TMRs or follow up. Furthermore, while not required, we encouraged sponsors to provide information on safe disposal of all medications, not just controlled substances, to MTM enrollees.

Section 6103 of the SUPPORT Act states that the information provided to beneficiaries regarding safe disposal of prescription drugs that are controlled substances must meet the criteria established in section 1852(n)(2) of the Act, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal. Section 1852(n)(2) states that the Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate to ensure that the information provided to an individual sufficiently educates the individual on the safe disposal of prescription drugs that are controlled substances. We described our proposed criteria and requirements for MA plans to furnish information on safe disposal of controlled substances when providing an in-home health risk assessment and our proposal to codify these requirements in a new provision of the regulations at § 422.111(j) in section III.C. of the proposed rule. In section III.E.2 of the proposed rule, we proposed that Part D plans would be required to furnish materials in their MTM programs regarding safe disposal of prescription drugs that are controlled substances that

meet the criteria specified in § 422.111(j). Under this proposal, Part D plans, like MA plans, would retain the flexibility to refine their educational materials based on updated information and/or on beneficiary feedback, so long as the materials meet the proposed criteria. Section 1860D-4(c)(2)(B)(ii) of the Act expressly directs that the information on safe disposal furnished as part of an MTM program meet the criteria established under section 1852(n)(2) of the Act for MA plans. Accordingly, to ensure consistency and to avoid burdening MA-PD plans with creating separate documents addressing safe disposal for purposes of conducting in-home health risk assessments and their MTM programs, we explained our belief that it is appropriate to apply the same criteria that would apply under the proposed provision at § 422.111(j) to MTM programs by including a reference to the requirements of § 422.111(j) in the regulation at § 423.153(d) governing MTM programs.

Specifically, we proposed to revise § 423.153(d)(1)(vii) to include a requirement that all MTM enrollees receive at least annually, as part of the CMR, a TMR, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal that meets the criteria in § 422.111(j).

Comment: A few commenters suggested that plans be allowed to include information on safe disposal in documents other than the TMR or CMR, or on a plan website. Another commenter suggested that the MTM program welcome letter (or written initial offer of the CMR) be used to convey safe disposal information as well, and asked if doing so would meet the intent of this requirement. This commenter stated that plans may have difficulty reaching beneficiaries after enrollment in the MTM program if they have disenrolled from the plan for any reason, and it would be useful for plans to have more ways to provide this important information.

Response: As an initial matter, we note that plans have no obligation to provide MTM services to beneficiaries once they have disenrolled from the plan. Given the importance of information on the safe disposal of medicines, we support posting the information on plan or

network pharmacy websites, but we do not believe that website postings alone will fulfill the statutory requirement that the information be provided to individual MTM recipients. However, we do agree with the comment recommending that safe disposal information could be provided in an MTM program welcome letter. While the statutory language at section 1860D-4(c)(2)(B)(ii) of the Act does not identify a specific format for providing this information, CMS believes that using the MTM welcome letter meets the statutory intent. Beneficiaries would then have an opportunity to ask any clarifying questions during a follow-up MTM service, including during the CMR. While not specifically addressed in the comments received, we would also support sending the safe disposal information electronically, for example through a member portal, provided the plan can document that the individual received the information. Accordingly, in this final rule we are modifying the proposed regulation text at § 423.153(d)(1)(vii)(E) by including a reference to "other MTM correspondence or service" to give plans the flexibility to provide this information in the manner they determine is most effective for reaching the beneficiaries enrolled in their MTM program.

Comment: All those who commented on the proposed requirement to include materials on safe disposal were supportive of the concept. A few commenters expressed appreciation that the proposed requirements in § 423.153(d) echoed those proposed in § 422.111(j). Some also commented that newly-developed disposal technologies that make the medications unusable, such as in-home deactivation kits, provide a viable option for safe disposal of controlled substances, and supported requiring information about these options in the educational materials.

Response: We appreciate commenters' support for the concept of furnishing information on safe disposal to MTM enrollees. We agree that the types of products referenced by the commenters may present additional means for safe disposal of prescription drugs that would complement the approaches described in the proposed rule. Therefore, as discussed in section III.C of this preamble, in this final rule we are modifying the proposed regulation text at § 422.111(j)(5) to permit plans to include information about the availability of in-home

deactivation kits in the enrollee's community, where applicable. MA-PD plans will be able to use the same communication materials on safe disposal to educate MTM enrollees as they use for enrollees receiving this information as part of an in-home health risk assessment under MA.

After consideration of the comments received, we are finalizing the proposed changes to the Part D MTM program requirements with the modifications discussed. We are finalizing our proposal to expand the definition of beneficiaries targeted for enrollment in MTM programs at § 423.153(d)(2) to include ARBs, as defined in § 423.100. We are finalizing the provision at § 423.153(d)(1)(vii)(E) with modifications to allow plans to meet the safe-disposal educational requirement through use of a CMR, TMR, or other MTM correspondence or service, such as an MTM welcome letter. We are finalizing as proposed the requirement at § 423.153(d)(1)(vii)(F) specifying that the information provided must comply with all requirements of § 422.111(j). Lastly, we are modifying the regulation text at § 423.153(d)(1)(vii)(E) and § 423.153(d)(2)(ii) to specify that these requirements are applicable beginning on January 1, 2022. As noted in the Executive Summary of this final rule, the revisions to §423.153(d)(2) as a whole are applicable 60 days from the date of publication in the Federal Register.

E. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CARA amended the Act to include new authority for Medicare Part D drug management programs effective on or after January 1, 2019. If an enrollee is identified as at-risk under a drug management program (DMP), the individual has the right to appeal an at-risk determination under the rules in part 423, subparts M and U. In addition to the right to appeal an at-risk determination, an enrollee has the right to appeal the implementation of point-of-sale claim edits for frequently abused drugs that are specific to an ARB or a limitation of access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers or dispensed to the beneficiary by one or more network pharmacies (lock-in). Section 2007 of the SUPPORT Act amended section 1860D-4(c)(5) of the Act to require that, if

on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the independent outside entity contracted with the Secretary for review and resolution.

To implement the changes required by the SUPPORT Act, we proposed to revise the requirements related to adjudication timeframes and responsibilities for making redeterminations at § 423.590 by adding paragraph (i) to state that if on redetermination the plan sponsor affirms, in whole or in part, its decision related to an at-risk determination under a DMP in accordance with § 423.153(f), the plan sponsor must forward the case to the IRE by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of § 423.590. We also proposed revisions to the requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*). Specifically, we proposed that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution.

Finally, we proposed to revise § 423.600(b) to clarify that the requirement that the IRE solicit the views of the prescribing physician or other prescriber applies to decisions that are auto-forwarded to the IRE.

We summarize the comments we received on these proposals related to automatic escalation and respond to them as follows.

Comment: Several commenters expressed support for our proposal that if on redetermination a plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a DMP in accordance with § 423.153(f), the plan sponsor must forward the case to the IRE for review and resolution**.** One commenter noted that it has been their experience in general that most patients do not formally contest their at-risk determination status, but the commenter supports a beneficiary's right to appeal. Some of the commenters that supported the proposal related to auto-escalation of these cases to the IRE also expressed specific concerns. A

few commenters noted that requiring denied cases to be forwarded to the IRE by the expiration of the applicable adjudication timeframe will significantly decrease the amount of time that plans have to review at-risk redeterminations. These commenters stated that these types of cases generally take longer to complete due to more outreach and coordination between providers than other types of redetermination cases and that reducing the timeframe to complete these cases in order to prepare a case for the IRE will decrease the quality of the plan's review. One commenter stated the belief that CMS's proposed timeframe for auto-escalation is not realistic or achievable, noting that DMP cases are complicated, and multiple delegated entities must coordinate to prepare a complete case file for forwarding. Commenters stated that plans need time to prepare case files and to ensure their completeness by acquiring the complete case management information from the DMP team, and that plans should have the full adjudication time for review of these cases.

Commenters noted that, in situations where a plan affirms its denial of an at-risk determination, it would pose operational burden and challenges to complete a thorough investigation, reach a determination, and automatically forward the case to the IRE within the 72-hour adjudication timeframe for expedited determinations and the 7-day timeframe for standard at-risk determinations. A couple of commenters noted that plans are afforded 24 hours after the expiration of the adjudication timeframe to prepare and forward the case file to the IRE in those Part D benefit appeal cases in which the plan misses its adjudication timeframe. Some of the commenters suggested that plans be afforded 24 hours to prepare and send the case file to the IRE and other commenters suggested 48 or 72 hours from the end of the adjudication timeframe. A commenter believes that the process of automatic escalation to external review should be consistent with Part D requirements for standard or expedited requests, so as to mitigate any additional administrative burden and requests that CMS ensure that this process mirror Part D requirements so that the systems and policies in place are seamless.

Response: We thank the commenters for their overall support and agree with those commenters who expressed concern that requiring the administrative case file to be assembled and forwarded to the IRE within the applicable adjudication timeframe could unnecessarily curtail the amount of time a plan has to conduct a thorough review of the case. The regulations at § 423.590(c) and (e) that govern Part D benefit redeterminations require a case to be auto-forwarded to the IRE when the plan misses the adjudication timeframe. Specifically, a plan has 24 hours from the end of the applicable adjudication timeframe to send the case file to the Part D IRE. For consistency with how cases currently subject to auto-forwarding to the IRE are handled, we believe it is reasonable and permissible under the statute to allow plans up to an additional 24 hours after the expiration of the applicable redetermination adjudication timeframe to assemble and forward the administrative case file to the IRE. In this final rule, the proposed regulation text at § 423.590(i) has been modified to state that if on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

Comment: A few commenters disagreed with the proposals related to the DMP notices. Commenters stated that providing the appeal notification on the first notice does not add value to the beneficiary, since the first notice has a 30-day window to gain additional information, if necessary, before a final decision is made to implement a lock-in or POS edits. These commenters recommend that appeal language only be included on the second notice. To reduce member confusion, a few commenters urged CMS to consider addressing escalation to the IRE only in the second notice as it relates to redeterminations specifically, and to ensure that it is clear the IRE escalation process will only apply when a redetermination in whole or in part is denied. Commenters also noted that if CMS is going to update member notices for the DMP, it is critically important for plans to receive updates to the notices in a timely manner to allow

plans sufficient time to revise, implement, and test new notices. A few commenters also requested that CMS update the model redetermination denial notice to account for auto-forwarding of an adverse DMP case to the Part D IRE.

Response: We thank the commenters for their perspective on the notices intended to inform at-risk beneficiaries of their rights under a plan sponsor's DMP. We proposed that the initial and second notice explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. SUPPORT Act section 2007 specifically requires that notice of the automatic escalation of adverse decisions be included on the initial and second notice. Therefore, we do not believe we have the discretion to omit information on this right from the initial notice, as suggested by some of the commenters. With respect to the model redetermination notice, we plan to update that model consistent with this final rule. However, we note that this notice is a model that plan sponsors have the discretion to modify.

Comment: A few commenters requested that CMS train the IRE appropriately to ensure consistent reviews of drug management cases. One commenter noted that these are unique case reviews and cannot simply be overturned by the IRE based on a provider attestation of medical necessity. The commenter also stated that the IRE should have specific criteria in place to conduct these reviews and, further, that plans should also have recourse to address instances when the IRE overturns a plan decision.

Response: We thank the commenter for these comments and note that the IRE is already conducting reviews of DMP cases based on published regulations and guidance that govern plan sponsor activities with respect to drug management programs. The IRE review function is a beneficiary protection set forth in statute and there may be instances where the independent review performed by the IRE will result in a plan's decision being overturned based on a finding of medical necessity given the facts and circumstances of the enrollee's case, including clinical

information furnished by the enrollee's prescriber. If a plan believes the IRE has made an error in its decision making, the IRE's reconsideration decision may be reopened consistent with the rules at § 423.1980.

Comment: A couple of commenters expressed support for the proposal to require automatic escalation of DMP to external review, but also urged the Secretary to either exercise his authority or support legislation to extend such auto-escalation to external review for all adverse appeal decisions regarding Part D drugs, similar to the rules applicable to Medicare Advantage appeals.

Response: We appreciate the commenters' support for the proposed rules related to automatic escalation of DMP appeals, but note that the comment related to extending automatic escalation to all Part D benefit appeals is outside the scope of this rule.

Comment: While recognizing that the automatic escalation provision is required under the SUPPORT Act, some commenters expressed specific concerns with this proposal. One commenter encouraged CMS to find a path that allows the beneficiary to exercise their appeal rights following the standard appeals process outlined in Part C and D guidance, as must all other Medicare beneficiaries who receive an adverse redetermination. The commenter stated that the SUPPORT Act creates a discrepancy in the uniformity of the Medicare benefit by devising a unique process for ARBs to have their denied redeterminations automatically auto-forwarded to the IRE. The commenter stated that CMS should clarify how the IRE might reach a decision other than the decision the plan reached in consultation with the at-risk beneficiary's prescriber and requested that CMS share with plans the additional data sources the IRE may have that plans will not. The commenter also requested that CMS provide plans any training materials that may be provided to the IRE to help process these reconsiderations. Another commenter expressed concern that the process of automatic escalation to an external reviewer sets up the patient's care for review involving third parties who may be unreasonably biased with an anti-opioid mindset

and incentivized by institutional conflicts of interest, such as the reduction of costs to insurance companies. This commenter also noted that it has been his experience that outside reviews fail to reflect adequate perspective on the patient, their problems, and their care and that the process inevitably involves the patient or their doctor negotiating a complex and time consuming phone triage system and may require an hour or more of a physician's time.

Response: We appreciate the comments, but note that the automatic escalation of a beneficiary's case to the IRE is a statutory provision that creates a protection for beneficiaries who are in a DMP. Part of the competitive process of contracting with an outside independent entity involves consideration of any potential institutional conflicts of interest. The very nature of an outside independent review means that there may be cases where the IRE reaches a different decision from that reached by a plan, based on clinical information supplied by the enrollee's prescriber. The IRE is required to follow the same regulations and guidance related to DMPs as is followed by plan sponsors. There may be instances where the IRE's review of supporting documentation received from an enrollee's prescriber reasonably supports a different decision from that reached by the plan sponsor. With respect to the time an enrollee or prescriber may have to expend, automatic escalation to IRE review should reduce the time a beneficiary has to spend disputing a limitation on access under a DMP because, under this final rule, the beneficiary will no longer have to request IRE review. In addition, the IRE is required to solicit the views of the prescribing physician or other prescriber when it receives a case from a plan sponsor, which may reduce the time a physician or other prescriber will have to expend providing necessary clinical information to the IRE.

Comment: A commenter asked CMS to clarify how an ARB will exercise his or her appeal rights and whether the auto-forwarded denied appeal be considered the first level of appeal.

Response: As with Part D benefit appeals, an ARB exercises his or her right to appeal by requesting a redetermination from the plan, which is the first level of appeal. The IRE review is the second level of appeal, including those DMP cases that will be subject to auto-forwarding under this final rule.

Comment: A commenter questioned what the impact will be if the plan does not auto-forward the denied appeal within the required timeframe.

Response: The SUPPORT Act requires plans to auto-forward to the IRE for review and resolution those redeterminations where a plan affirms its denial, in whole or in part. As with other regulatory requirements, CMS can exercise enforcement authority to ensure plan compliance. Pursuant to contract provisions at § 423.505(b)(7), plan sponsors must comply with all requirements of 42 CFR part 423, subpart M governing coverage determinations, grievances, and appeals, and formulary exceptions and CMS may impose sanctions on any plan sponsor with a contract for violations listed in § 423.752(a).

Comment: A commenter questioned how these auto-forwarded redeterminations will be differentiated by CMS from other reviews forwarded to the IRE and requested that CMS clarify whether the auto-forwarded denial or the IRE's decision on the auto-forwarded redetermination will be included in reporting or audit universes.

Response: Adverse redetermination decisions related to coverage limitations imposed under a plan sponsor's DMP that will be auto-forwarded to the IRE consistent with this final rule will be reported by plan sponsors as adverse redetermination decisions. For purposes of any necessary data gathering, the Part D IRE will be able to distinguish cases that are auto-forwarded for untimeliness from the DMP appeals auto-forwarded to the Part D IRE. With respect to the audit universes, if a plan sponsor's decision was made during the relevant universe period, those redeterminations will be reported in the redeterminations universe. If the determination was

fully or partially overturned by the IRE, ALJ, or MAC during the relevant universe period, the overturn decision will be reported in the Part D effectuations of overturned decisions universe.

Comment: Some commenters suggested that CMS define what a plan sponsor is to include in a case packet for auto-forwarded denials.

Response: We appreciate the commenters' suggestion and note that the Part D IRE's reconsideration procedures manual and case file transmittal form lists the documents that should be included by plan sponsors as part of the administrative case file. These documents will be updated, as necessary. For example, the case file transmittal form will be modified so that a plan sponsor can clearly indicate that a case is being automatically forwarded to the Part D IRE as a result of an adverse DMP redetermination.

Comment: A commenter asked whether the plan is required to notify the ARB, their prescriber(s) or others and, if so, questioned if there is a required timeframe to complete the notification.

Response: Redetermination decisions related to a denied redetermination involving a DMP are subject to existing notice requirements at §§ 423.590(a)(d) and (g).

Comment: A commenter who expressed support for the proposal requested clarification on whether the Part D sponsor or the Part C plan would be responsible for making this determination when the member is enrolled in a standalone PDP. The commenter requested clarification on whether it is the Part D sponsor's responsibility to forward a redetermination to IREs for all drugs for any member enrolled in a DMP. We believe the commenter is asking about a situation where an individual is enrolled in an MA plan and a separate, standalone Part D drug plan and whether it is the responsibility of the standalone Part D drug plan to forward an adverse DMP plan appeal to the IRE.

Response: Consistent with section 1860D-4(c)(5)(E) of the Act, it is the responsibility of an enrollee's Part D plan sponsor to auto-forward to the IRE an adverse redetermination decision related to an individual's identification as an ARB, a coverage determination made under a DMP, the selection of prescriber or pharmacy under the DMP and information to be shared for subsequent plan enrollment.

Comment: A commenter that expressed support for automatically escalating redeterminations associated with DMP appeals to the Part D independent review entity (IRE) noted that automatically escalating an appeal for an at-risk determination to an IRE without having to wait for the enrollee or prescriber on their behalf to request a review will serve to reduce the lag time in final determinations being issued and enable patients to access needed care sooner. This commenter also noted support for proposed changes to the required initial and second notice in addition to adjudication timeframes and redetermination responsibilities. This commenter encouraged us to reiterate the need for the prescribing physician to provide all requested information associated with the adverse decision to the IRE within a timely manner. Further, the commenter urged us to consider requiring the IRE to make a good faith effort to obtain relevant information from the prescribing physician in instances in which there is not an automatic escalation as well to ensure consistency in the resolution of all cases involving Part D appeals.

Response: We appreciate the support for these proposals and agree that it is important for the prescriber to submit the clinical information necessary for a thorough adjudication of the case. In this final rule, we are finalizing our proposal to modify the existing regulations at § 423.600(b) such that the requirement that the IRE solicit the views of the prescribing physician or other prescriber and include a written account of the prescriber's views in the IRE's record will apply to adverse DMP redeterminations that will be auto-forwarded to the IRE.

Comment: A commenter expressed the belief that automatic escalation to the IRE weakens the authority of Part D plans as partners to CMS in the fight against the opioid epidemic. An ARB appealing a decision to lock them into a specific pharmacy for opioid prescriptions would essentially "skip the line" if a plan denies their appeal and then upholds the denial upon review. The commenter stated the belief that this is unfair to non-ARBs, who must then wait behind ARBs for an IRE decision. The commenter also believes that this diminishes the ability of the plan to impact the behavior of providers and that rather than making changes to prescribed therapies, providers will wait for the result of the redetermination. Further, commenter believes that automatic escalation removes the ability of the plan to reconsider its decision when more information is submitted to it. The commenter also believes that automatic escalation will increase denials because the turnaround time clock will expire prior to the IRE having full information, and the beneficiary's denial is likely to be upheld. The commenter recommends, to the extent that CMS cannot relax the requirements in this final rule, that CMS provide the IRE with opioid-specific training prior to receiving these automatically escalated cases, to minimize process-related denials. The commenter recommends that CMS broadly consider a creative approach to meeting the statutory intent behind this provision and delay its implementation, or at least enforcement, until it can implement a policy that does not punish Part D plans and does not punish beneficiaries (at-risk and otherwise) while appropriately administering the pharmacy lock-in program.

Response: As previously stated, the SUPPORT Act requires plan sponsors to auto-forward adverse DMP redeterminations to the IRE for review and resolution. We do not believe we have the discretion to interpret the statutory language in a manner that results in a plan sponsor not being required to auto-forward a denied DMP redetermination to the IRE for review and resolution. We continue to believe that, given the extensive case management involved in these types of cases, there will be very few cases that will be subject to auto-forwarding. We note that the IRE is already performing reviews of DMP cases based on existing regulations and

guidance. We believe the intent of the SUPPORT Act provision requiring automatic escalation to the IRE is to enhance protections for at-risk beneficiaries and not intended to "punish" plans or beneficiaries. We disagree that this requirement weakens a plan sponsor's authority to partner with CMS in the fight against the opioid epidemic. As we've previously noted, the extensive case management involved with DMPs affords plans ample opportunity to work with an ARB to ensure appropriate limitations and will likely result in a very low volume of appeals.

Based on the comments we received, we are finalizing, with modification, our proposal to require a Part D plan sponsor to auto-forward to the IRE those redeterminations where a plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a DMP in accordance with § 423.153(f). Consistent with existing processes for untimely cases that are auto-forwarded to the IRE, we are modifying our proposal to state in this final rule that plans will be required to forward adverse DMP redetermination decisions to the IRE within 24 hours after expiration of the applicable adjudication timeframe. In addition, we are finalizing the proposed revision at § 423.600(b) that will apply the requirements related to the IRE soliciting the views of the prescribing physician or other prescriber if a case is forwarded to the IRE by a Part D plan sponsor. We are also finalizing the proposed requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*) to require that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. Finally, necessary modifications will be made to the Part D IRE's contract consistent with these final rules and related operational issues will be addressed in the IRE's reconsideration procedures manual. Pursuant to section 2007 of the SUPPORT Act, the automatic escalation provisions being finalized in this rule – at § 423.153(f)(5)(ii)(C)(*3*), § 423.153(f)(6)(ii)(C)(*4*)(*iii*), § 423.590(i), and § 423.600(b) – apply 60 days following publication of this final rule.

F. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud

and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

1. Medicare Parts C and D Anti-Fraud Efforts

CMS's role in overseeing the Medicare program includes ensuring that payments are made correctly and that fraud, waste, and abuse are prevented and detected. Failure to do so endangers the Trust Funds and may result in harm to beneficiaries. CMS has established various regulations over the years to address potentially fraudulent and abusive behavior in Medicare Parts C and D. For instance, 42 CFR 424.535(a)(14)(i) addresses improper prescribing practices and permits CMS to revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part B or D drugs that is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both.

2. SUPPORT Act – Sections 2008 and 6063

a. Background

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The Centers for Disease Control and Prevention (CDC) estimated 47,000 opioid overdose deaths in 2017, and 36 percent of those deaths involved prescription opioids.[21] On October 26, 2017, the Acting Health and Human Services Secretary, Eric D. Hargan, declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[22] This public health emergency has since been renewed several times by Secretary Alex M. Azar II.[23]

Section 2008 of the SUPPORT Act amends and adds several sections of the Act to address the concept of a "credible allegation of fraud." Specifically:

- Sections 2008(a) and (b) of the SUPPORT Act amends sections 1860D-12(b) and

[21] https://www.cdc.gov/drugoverdose/data/index.html.
[22] https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.
[23] https://www.phe.gov/emergency/news/healthehactions/phe/Pages/opioid-19apr2019.aspx

1857(f)(3) of the Act, respectively, by adding new requirements for Medicare Part D plan sponsors and MA organizations offering MA-PD plans. Specifically, the provisions--

++ Apply certain parts of section 1862(o) of the Act, regarding payment suspensions based on credible allegations of fraud, to Medicare Part D plan sponsors and MA organizations offering MA-PD plans, allowing them to impose payment suspensions on pharmacies in the same manner as these provisions apply to CMS.

++ Require these Part D plan sponsors and MA organizations offering MA-PD plans to notify the Secretary regarding the imposition of a payment suspension on a pharmacy pending an investigation of a credible allegation of fraud (but does not extend the requirement to report to the Secretary other payment suspensions for which plan sponsors already have authority).

++ Require this notification to be made such as via a secure internet website portal (or other successor technology) established under section 1859(i).

• Section 2008(d) of the SUPPORT Act, which amended section 1862(o) of the Act, states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

Although the effective date for these provisions of section 2008 of the SUPPORT Act is for plan years beginning on or after January 1, 2020, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary due to several factors. The first factor is the need to ensure that the web-based portal is complete and operational for plan sponsor's use. While the development of the web-based portal began when the legislation was enacted, CMS was unable to complete the development of the portal in time for its full implementation in plan year 2021. In addition, the portal has required several key updates to reflect the requirements in this regulation. Additional factors include the need to ensure the web-based portal is complete and operational for plan sponsor's use; the time needed for plan sponsors to determine internal procedures to meet the requirements outlined in this rule; the need for CMS to obtain feedback from plan sponsors to

address any challenges encountered with the web-based portal; and the need to provide plan sponsors with the opportunity to address any other operational challenges with implementing these provisions, including potential changes that may be needed due to the COVID-19 public health emergency. Furthermore, the applicability date is later than the effective dates in the SUPPORT Act because the publication of this final rule is occurring after the bid deadline for plan year 2021. However, where the statute is self-implementing, the delay in applicability of these regulations is not a barrier to enforcement of the statutory provisions.

Section 6063(a) of the SUPPORT Act, which added a new paragraph (i)(1) to section 1859 of the Act, requires the following:

• The Secretary, after consultation with stakeholders, shall establish a secure web-based program integrity portal (or other successor technology) that would allow secure communication among the Secretary, MA plans, and prescription drug plans, as well as eligible entities with a contract under section 1893, such as Medicare program integrity contractors. The purpose is to enable, through the portal:

++ The referral by such plans of substantiated or suspicious activities (as defined by the Secretary) of a provider of services (including a prescriber) or supplier related to fraud, waste, or abuse for the purpose of initiating or assisting investigations conducted by the eligible entity; and

++ Data sharing among such MA plans, prescription drug plans, and the Secretary.

• The Secretary shall disseminate the following information to MA plans and prescription drug plans via the portal: (1) providers and suppliers referred for substantiated or suspicious activities during the previous 12-month period; (2) providers and suppliers who are currently either excluded under section 1128 of the Act or subject to a payment suspension pursuant to section 1862(o) or otherwise; (3) providers and suppliers who are revoked from Medicare, and (4) in the case the plan makes a referral via the portal concerning substantiated or suspicious activities of fraud, waste, or abuse of a provider or supplier, the Secretary shall notify the plan if the related providers or suppliers were subject to administrative action under title XI

or XVIII for similar activities.

• The Secretary shall, through rulemaking, specify what constitutes substantiated or suspicious activities of fraud, waste, or abuse, using guidance such as that provided in the CMS Pub. 100-08, Medicare Program Integrity Manual (PIM), chapter 4, section 4.8. In section 4.8 of the PIM, CMS provides guidance to its Medicare program integrity contractors on the disposition of cases referred to law enforcement. Similar to what is stated in section 2008(d) of the SUPPORT Act, a fraud hotline tip without further evidence does not constitute sufficient evidence for substantiated fraud, waste, or abuse.

• On at least a quarterly basis, the Secretary must make available to the plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. This information must be anonymized data submitted by plans without identifying the source of such information.

Although the effective date for these provisions of section 6063(a) of the SUPPORT Act is beginning not later than 2 years after the date of enactment, or by October 24, 2020, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary for the same reasons described previously in this section related to the provisions in section 2008 of the SUPPORT Act.

Furthermore, section 6063(b) of the SUPPORT Act, which amended section 1857(e) of the Act, requires MA organizations and Part D plan sponsors to submit to the Secretary, information on investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans, related to inappropriate prescribing of opioids. The Secretary shall, in consultation with stakeholders, establish a process under which MA organizations and Part D plan sponsors must submit this information. In addition, the Secretary shall establish a definition of inappropriate prescribing,

which will reflect the reporting of investigations and other corrective actions taken by MA organizations and Part D plan sponsors to address inappropriate prescribing of opioids and the types of information that must be submitted.

Although the effective date for these provisions of section 6063(b) of the SUPPORT Act is for plan years beginning on or after January 1, 2021, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary for the same reasons described previously in this section related to the provisions in section 2008 of the SUPPORT Act.

b. Need for Additional Measures

Existing regulations for MA and Part D plan sponsors in §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) specify that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs to CMS or its designee. (We note that § 422.503(b) generally outlines requirements that MA organizations must meet. Section 423.504(b) outlines conditions necessary to contract as a Part D plan sponsor.) Presently, MA organizations and Part D plan sponsors voluntarily report such data to CMS through either--(1) direct submissions to CMS, or (2) communication with the Investigations Medicare Drug Integrity Contractor (IMEDIC). Given the gravity of the nationwide opioid epidemic and the need for CMS and the plans to have as much information about potential and actual prescribing misbehavior as possible in order to halt such misbehavior, we are taking further regulatory action consistent with sections 2008 and 6063. Sections 2008 and 6063 of the SUPPORT Act provide the authority to establish regulations to implement a requirement for plans to report certain related data.

3. Proposed Provisions

Consistent with the foregoing discussion, we proposed the following regulatory provisions to implement sections 2008 and 6063 of the SUPPORT Act. As explained, some of our proposals modify or supplement existing regulations, while others establish new regulatory

paragraphs altogether. Regulations related to Part C are addressed in 42 CFR part 422; those pertaining to Part D are addressed in 42 CFR part 423. Regulations pertaining to or contained in other areas of title 42 will be noted as such.

a. Definitions

The definitions outlined in this section of this rule will be effective following the required statutory deadlines for each reporting piece described in the SUPPORT Act. In the proposed rule, we proposed the definitions of substantiated or suspicious activities of fraud, waste or abuse and fraud hotline tip would be effective beginning October 24, 2020, and the definitions of inappropriate prescribing of opioids and credible allegations of fraud would be effective beginning January 1, 2021.

(1) Substantiated or Suspicious Activities of Fraud, Waste, or Abuse

We indicated earlier that section 6063(a) of the SUPPORT Act added a new section 1859(i)(1) to the Act requiring the establishment of a regulatory definition of "substantiated or suspicious activities of fraud, waste, or abuse," using guidance such as that in CMS Pub. 100-08, PIM, chapter 4, section. 4.8. To this end, we proposed to add to §§ 422.500 and 423.4 a definition specifying that substantiated or suspicious activities of fraud, waste or abuse means and includes, but is not limited to allegations that a provider of services (including a prescriber) or supplier: engaged in a pattern of improper billing; submitted improper claims with suspected knowledge of their falsity; submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or is the subject of a fraud hotline tip verified by further evidence. Consistent with the reference in section 6063(a) of the SUPPORT Act to chapter 4 of the PIM, our proposed definition largely mirrored that in section 4.8 of the PIM. We also believe that this definition is, importantly, broad enough to capture a wide variety of activities that could threaten Medicare beneficiaries and the Trust Funds. We solicited public comment on this definition.

We received several comments on the definition of "substantiated or suspicious activities of fraud, waste or abuse" and our responses to those comments follow.

Comment: A professional organization supported this definition and mentioned that it would ensure targeted streamlined fraud reporting.

Response: We appreciate the comment and support of the definition and we are finalizing the definition as proposed.

Comment: Several commenters raised concerns with the definition of substantiated and suspicious activity. Some commenters requested additional information regarding the scope of the definition. One commenter recommended that CMS provide additional guidance on the definition of "pattern of improper billing." Other commenters wanted to know what specific criteria will be used for substantiated and suspicious reporting. Another commenter was concerned with CMS's use of language such as "substantiated" and "suspicious."

Response: In defining what constitutes substantiated or suspicious activities of fraud, waste, and abuse, we looked to guidance currently in the Medicare Program Integrity Manual 4.8. Section 6063 of the SUPPORT Act further clarifies that a fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse. We believe the definition that we are finalizing will address the commenters' concerns as it reflects the SUPPORT Act requirement to establish the definition using guidance such as that provided in the Medicare Program Integrity Manual 4.8. In an effort to be consistent across our programs, we believe the definition as proposed provides a similar context for what is to be reported as the PIM outlines for fee-for-service. Based on the comments received and our responses we are finalizing the proposed definition without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(2) Inappropriate Prescribing of Opioids

Section 6063(b) of the SUPPORT Act, as mentioned previously, states the Secretary is required to establish: (1) a definition of inappropriate prescribing; and (2) a method for determining if a provider of services meets that definition. MA organizations and Part D Plan Sponsors must report actions they take related to inappropriate prescribing of opioids. We accordingly proposed to add the following definition of inappropriate prescribing with respect to opioids to §§ 422.500 and 423.4. We proposed that inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D Plan Sponsors, there is an established pattern of potential fraud, waste and abuse related to prescribing of opioids, as reported by the Plan Sponsors.

In determining whether inappropriate prescribing of opioids has occurred we proposed that plan sponsors may consider any number of factors including, but not limited to the following: documentation of a patient's medical condition; identified instances of patient harm or death; medical records, including claims (if available); concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm; levels of Morphine Milligram Equivalent (MME) dosages prescribed; absent clinical indication or documentation in the care management plan, or in a manner that may indicate diversion; State level prescription drug monitoring program (PDMP) data; geography, time and distance between a prescriber and the patient; refill frequency and factors associated with increased risk of opioid overdose.

We believe the many steps that CMS, the CDC, and HHS have taken in response to the nation's opioid crisis have had an overall positive impact on clinician prescribing patterns, resulting in safer and more conscientious opioid prescribing across clinician types and across the settings where beneficiaries receive treatment for pain, and have also resulted in heightened public awareness of the risks associated with opioid medications. For example, recent HHS

guidance[24] highlights the importance of judicious opioid prescribing that minimizes risk and; urges collaborative, measured approaches to opioid dose escalation, dose reduction, and discontinuation; furthermore, a 2019 HHS Task Force report[25] outlines best practices for multimodal approaches to pain care. In this definition, we recognized that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing based on the clinician's professional judgement, including, the beneficiary's clinical indications and characteristics, whether the prescription is for an initial versus a subsequent dose, clinical setting in which the beneficiary is being treated, and various other factors. We sought public comments on specific populations or diagnoses that could be excluded for purposes of this definition, such as cancer, hospice, and/or sickle cell patients. Based upon widely accepted principles of statistical analysis and taking into account clinical considerations mentioned previously, we noted that CMS may consider certain statistical deviations to be instances of inappropriate prescribing of opioids. We requested evidence from clinical experts regarding evidence based guidelines for opioid prescribing across clinical specialties and care settings that could be considered to develop meaningful and appropriate outlier methodologies. Therefore, we proposed that inappropriate prescribing of opioids should be based on an established pattern as previously described in this section utilizing many parameters.

We solicited public comment on other reasonable measures of inappropriate prescribing of opioids.

We received numerous comments regarding the definition of inappropriate prescribing and on other reasonable measures of inappropriate prescribing of opioids and our responses follow.

Comment: Two professional associations supported the definition outlined in the rule.

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[24] "HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics" found at https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf

[25] https://www.hhs.gov/ash/advisory-committees/pain/index.html

Response: We appreciate the comments from prescribing professionals that also support our proposed definition. We will be finalizing the definition, as described in this final rule.

Comment: We received comments from one advocacy group which criticize the definition of "inappropriate prescribing". The comments made by the advocacy group were also referred to by several other individual commenters who endorsed their concerns. The advocacy group asserted that CMS's proposal contains an inappropriate view of the "risks" of opioid prescribing for people in pain, which could be used for denial of pain treatment." As an alternative, they recommend better training of physicians in the management of chronic pain. Furthermore, the commenters noted that HHS' actions have focused on "what is likely to be a minor problem (physician overprescribing)" instead of illegal drug use and abuse.

Response: Section 6063 of the SUPPORT ACT required us to adopt a definition of inappropriate prescribing of opioids. In response to the statement that overprescribing may be a minor problem, we disagree and cite a real example of how prescribing authority can be used inappropriately. In September 2019, federal law enforcement officials announced "charges against 13 individuals across five Appalachian federal districts for alleged offenses relating to the over prescription of controlled substances through 'pill mill' clinics. Of those charged, 12 were charged for their role in unlawfully distributing opioids and other controlled substances and 11 were physicians. The alleged conduct resulted in the distribution of more than 17 million pills." [26] In relation to concerns raised about provider education and training, we would note that the subject is out of scope for this regulation.

Comment: One commenter stated that CMS should consider certain statistical outliers and/or individual beneficiary cases of overutilization while another commenter stated that the definition of inappropriate prescribing must be limited to suspected fraud, not only outlier prescribing patterns. Another commenter noted that CMS should amend the proposed definition

[26] https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13

of inappropriate prescribing to "potential" with "material and repeated intentional acts of". Another commenter recommended that CMS add reasonable measures of inappropriate prescribing of opioids- for example, CMS should consider including any off-guideline use, including prescriptions for large quantities to opioid-naïve members. Another commenter believed that a peer physician from the same specialty, after considering specific patient needs, is most qualified to determine whether opioids have been prescribing appropriately. Another commenter was concerned that without specifically defining "inappropriate prescribing" a subjective approach may be taken in initiating actions involving suspicious activities that may warrant investigation.

Response: We believe the proposed rule was clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. The list of factors is not meant to be exhaustive list of factors that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. The information provided in the definition is sufficient and will assist the agency in identifying providers with patterns of potential fraud, waste and abuse related to opioid prescribing. It is important to note that most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids.

Comment: A few commenters believe the insurance companies' authority is too broad in determining inappropriate prescribing.

Response: The Medicare prescription drug benefit is delivered through Medicare Part D plans and many of the plan sponsors are insurance companies. We have considered industry guidelines and policies in defining inappropriate prescribing. Most Part D plan sponsors already have Special Investigative Units which have detection and prevention procedures in place to address cases of inappropriate prescribing of opioids.

Comment: A commenter stated that although the definition of inappropriate prescribing calls for a more comprehensive review, there are concerns that the focus will be on dose and quantity without consideration of other factors that affect patients and physicians.

Response: As we have stated in our previous responses to comments, we believe the proposed rule was clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. The list of factors is not meant to be an exhaustive list that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. In addition to the list of factors, we have also considered industry guidelines and policies in defining inappropriate prescribing. We believe the information provided is sufficient in assisting plans to identify established patterns of potential fraud, waste and abuse related to prescribing of opioids. As we stated previously in this section, most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids. However, under section 6063 of the SUPPORT Act, plans will now be required to report any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

Comment: There were numerous commenters who suggested that CMS consider exceptions such as Long Term Care, cancer survivors, high risk surgical patients, chronic pain, end stage chronic lung disease and rare genetic disorders, when reviewing for inappropriate prescribing. There were also comments that recommended that CMS consider prescriber specialties when defining inappropriate prescribing. One commenter suggested that CMS specify that the factors listed does not include an exhaustive list of patterns that would contribute to inappropriate opioid prescribing. A commenter also expressed concern that CMS creating blanket exclusions from the analysis has the potential for fraud and recommended that CMS not exclude any drug type, specific populations or diagnosis.

Response: As mentioned in the preamble, we recognize that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing. Cancer, hospice, and sickle cell patients have been identified as exclusions in other sections of the regulation, such as the updated drug management program provisions at § 423.100. To ensure that vulnerable populations continue to have access to care, we are finalizing the proposed definition of inappropriate prescribing with a modification such that beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services will be exempt from consideration for the inappropriate prescribing of opioids. We clarify that LTC, in this context, means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act. These exemptions were added to be consistent with other areas of the proposed regulation as well as the current regulatory exemptions at § 423.100. However, just as plan sponsors may consider a number of factors such as MME levels, concurrent prescribing of opioids with an opioid potentiator, and time and distance between the prescriber and the patient when determining inappropriate prescribing of opioids, plan sponsors may also apply the same judgement when considering other diseases or clinical factors or scenarios that have not been listed in the definition. Plan sponsors should use all information available to them in determining inappropriate opioid prescribing. These exclusions also do not preclude plan sponsors from reporting on a voluntary basis under §§ 422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(G*)*(3).

Comment: Several comments were received in response to use of MME levels as a factor in determining opioid overprescribing. Commenters were concerned that CMS does not exempt opioid use disorder treatment from MME guidelines. Another commenter stated a consensus definition of MME dosages does not exist and expressed concern with a policy that allows Plan Sponsors to rely on MME dosages. Another commenter mentioned that the MME is not an

appropriate factor in determining abuse. A commenter suggested excluding MME levels as a factor in any analysis of inappropriate prescribing.

Response**:** We believe the proposed rule is clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. Most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids. It is our understanding that MME are already utilized as part of many plan sponsors measures to address FWA. As such, we believe MME is an important factor that might be considered when identifying inappropriate prescribing of opioids. The list of factors is not meant to be an exhaustive list of factors that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. The information provided in the definition is sufficient in assisting plans to identify established patterns of potential fraud, waste and abuse related to prescribing of opioids.

Comment: There were comments seeking clarification regarding if a pharmacy would be considered a provider and could be identified as having "Inappropriate Prescribing of Opioids," or if this proposed policy would only refer to actual medical professionals who can prescribe opioids.

Response: Based on the comments, there may be some misunderstanding of the reporting requirements cited in section 2008 of the SUPPORT Act versus section 6063 of the SUPPORT Act. Section 2008 of the SUPPORT Act requires plan sponsors to notify the Secretary of the imposition of a pharmacy payment suspension that is based on a credible allegation of fraud. That reporting will be done using a secure website portal. Section 6063 of the SUPPORT Act requires reporting information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. For purposes of section 6063(b), plan sponsors may consider a pharmacy a supplier.

Comment: Commenters expressed concern with the use of geography, time and distance

between the prescriber and the patient as a factor for opioid overprescribing. Specifically, one commenter stated that many people are forced to travel long distances not because of doctor shopping or pharmacy hopping, but because pain clinics have been shut down and primary doctors are refusing to see pain patients. Another commenter stated that for people with complex disabilities, geographically distant specialists may be the best (or only) care providers available. Another commenter stated that absent of fraud, high dosage and distance should not be considered indicators of inappropriate prescribing.

Response: We realize that there may be some circumstances in which a beneficiary may travel a considerable distance for access to a pharmacy or provider, for legitimate reasons. Plan sponsors may consider any number of factors when determining what constitutes inappropriate prescribing of opioids, in addition to geography time and distance. The list included in the proposed rule is not meant to be an exhaustive list of factors that may be used in the identification of fraud waste and abuse related to inappropriate prescribing of opioids.

Comment: We received several comments stating that illicit drugs, not prescription drugs, have contributed to the opioid crisis. Commenters also requested that CMS monitor to ensure that these actions do not encourage providers to be unnecessarily conservative when prescribing opioids which could limit access to older adults. Commenters also noted that CMS should encourage plan sponsors to align best practices, as published in the HHS Pain Management Best Practices Inter-Agency Task Force report.

Response: In response to the statement that illicit drugs, not prescription drugs, have contributed to the opioid, we disagree and cite a real example of how prescribing of prescription opioids can be used inappropriately. In September 2019, federal law enforcement officials announced "charges against 13 individuals across five Appalachian federal districts for alleged offenses relating to the over prescription of controlled substances through 'pill mill' clinics. Of those charged, 12 were charged for their role in unlawfully distributing opioids and other controlled substances and 11 were physicians. The alleged conduct resulted in the distribution of

more than 17 million pills."[27] Our proposed provisions are to ensure that fraud, waste, and abuse are prevented and detected and our Medicare population is protected from harm from opioid prescriptions. We have established several regulations over the years to promote patient safety and address potentially fraudulent and abusive behavior in Medicare Parts C and D. We are considering ways to effectively monitor the impact of these provisions. The provisions in the SUPPORT Act that we proposed to implement will add additional ways to ensure effective monitoring and oversight of prescribing practices related to opioids.

Based on the overwhelming feedback from health plans, professional societies, advocacy groups and individuals, we have determined there is a need to add exemptions when determining inappropriate prescribing of opioids. While there is no way to include every possible disease state that could be considered, we will add beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services as exclusions. These disease states were selected not only because they are clinically applicable but they align with existing exemptions in other CMS policies, such as the updated drug management program provisions at § 423.100. In addition, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(3) Credible Allegation of Fraud

Somewhat similar to section 6063(a) of the SUPPORT Act, section 2008(d) of the SUPPORT Act states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud. The term "credible allegation of fraud" is currently defined at §§ 405.370 and 455.2 (which, respectively, apply to Medicare and Medicaid) as an allegation from any source including, but not limited to the following: (1) fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations

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27 https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13

are considered to be credible when they have indicia of reliability, and, in the case of § 455.2, the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

To address the requirements of section 2008(d) of the SUPPORT Act, we proposed to revise the term "credible allegation of fraud" in §§ 405.370 and 455.2 as follows. We proposed that the existing version of paragraph (1) in both §§ 405.370 and 455.2 would be amended to state "Fraud hotline tips verified by further evidence." The existing version of paragraph (2) and (3) would remain unchanged. Similarly, we proposed to add in § 423.4 a definition of credible allegation of fraud stating that a credible allegation of fraud is an allegation from any source including, but not limited to: fraud hotline tips verified by further evidence; claims data mining; patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. In the case of § 423.4, we proposed that examples of claims data mining would include, but are not limited to, prescription drug events and encounter data mining. We solicited public comment on this definition.

We received several comments on the definition of Credible Allegation of Fraud and our responses follow.

Comment: A professional organization supported the proposed revised definition of credible allegation of fraud.

Response: We appreciate the comments from prescribing professionals that also support our proposed definition. We are finalizing the definition, as proposed in this final rule.

Comment: A commenter expressed concern that a credible allegation results in damage to the professional reputations of doctors and pharmacists.

Response: We note that credible allegation of fraud in this context is used when plan sponsors are implementing payment suspensions of pharmacies. Plan sponsors already have the authority to implement a payment suspension at their discretion according to their contracts with

the pharmacies. When they implement a payment suspension that is based on a credible allegation of fraud and meets the regulatory definition, now they must report it to CMS. We have defined credible allegations of fraud under § 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent is to only apply definitions for MA and Part D plans that are consistent with regulatory standards that are applied to both traditional Medicare and Medicaid. Accordingly, plan sponsors currently impose payment suspensions based on credible allegations of fraud and we recognize that MA and Part D plans currently use multiple sources in determining what may be considered "credible allegation of fraud" as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse.

Comment: Some commenters requested that CMS provide examples of credible evidence and provide clarification on the standards, thresholds and responsible party for reporting. One commenter believes that examples will assist plans in determining credible allegations of fraud and address fraudulent opioid prescribing. Another commenter recommended that CMS proactively communicate with plans on fraud schemes to assist in enhancing the plans oversight efforts.

Response: The regulations are being amended as specified in the SUPPORT Act section 2008(d) to extend a consistent regulatory definition for MA and Part D plans. We have defined credible allegations of fraud under 405.370 in previous rulemaking. As noted previously, the Plans will be required to report payment suspensions of pharmacies to CMS based on credible allegations of fraud. Accordingly, we recognize that MA and Part D plans currently may use a variety of sources in determining what may be considered "credible allegation of fraud" as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse. We also conduct regular training and education for Plan Sponsors on fraud detection and prevention and provides opportunities for the Plans to share information on fraud schemes. Therefore, we will continue to allow plans the flexibility in determining credible allegations of

fraud and will finalize this provision without additional examples other than what is currently defined.

Comment: A commenter recommended amending the proposed definition of credible allegation to an allegation from a plan of a material and repeated pattern of intentional violations of law or regulations that has been confirmed beyond suspicion through independent evidence. Allegations by third parties, including False Claims Act cases, law enforcement investigations and provider audits shall not constitute credible allegations of fraud.

Response: We have defined credible allegations of fraud under 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent of this provision is to implement the SUPPORT ACT which extends a consistent definition for MA and Part D plans. Accordingly, we recognize that MA and Part D plans currently use a variety of sources in determining what may be considered "credible allegation of fraud" as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse. We will proceed as noted previously in this section with finalizing the proposed definition without modification.

Comment: An association supported the proposed revision of the regulatory definition of credible allegation of fraud described in the proposed rule, changing "fraud hotline complaints" to "fraud hotline tips verified by further evidence." Another association also specifically supported our proposal that a fraud hotline top without further evidence shall be not be treated as credible allegation of fraud.

Response: We appreciate the support for the proposal to further define credible allegation of fraud by expanding the definition of fraud hotline complaint to fraud hotline tips verified by further evidence. We believe this will further assist plans in determining cases of fraud.

Comment: A commenter recommended that CMS provide training programs for health plan fraud units and guidance regarding the definition of credible allegation.

Response: We have defined credible allegations of fraud under 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent is to only establish similar and consistent definitions for MA and Part D plans. We conduct regular training and education for Plan Sponsors on fraud detection and prevention and provides opportunities for the Plans to share information on fraud schemes. We recognize that MA and Part D plans currently use a variety of sources in determining what may be considered "credible allegation of fraud" as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse.

Comment: A commenter specifically did not support the definition of credible allegation of fraud given that further evidence is not defined.

Response: The definition uses plain language and is intended to allow flexibility since evidence to corroborate the fraud hotline complaint or tip would vary on a case by case basis. Additionally, Part D sponsors have systems in place and experience with the evaluation and verification of fraud hotline tips.

Based on the comments received and our responses we are finalizing the provision as proposed without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(4) Fraud Hotline Tip

Sections 2008(d) and 6063(a) of the SUPPORT Act require the Secretary to define a fraud hotline tip. To this end, we proposed to add to §§ 405.370, 422.500, 423.4, and 455.2 a plain language definition of this term. We proposed that a fraud hotline tip would be defined as a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the federal government's HHS Office of the Inspector General (OIG) Hotline or a health plan's fraud hotline. This definition is intended to be broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's fraud hotline. Many private plans, which have their own fraud reporting

hotlines, participate as plan sponsors in Medicare Part D and this definition would seek to reflect their processes for reporting information on potential fraud, waste and abuse. We solicited public comment on this definition.

We received several comments on the definition of Fraud Hotline Tip. Our responses to those comments follow.

Comment: Several commenters supported the proposed definition of a fraud hotline tip including a professional association. Commenters that were supportive agreed that this definition will assist plans on ensuring investigative measures are taken and focus on those that indicate fraud.

Response: We appreciate the support and feedback on the proposal to further define a fraud hotline tip. As mentioned in the proposed rule we believe the definition is broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's hotline.

Comment: A commenter also recommended that CMS provide examples of other communications that may be submitted through a fraud reporting phone number or website.

Response: As mentioned in the proposed regulation, the definition is intended to be broad in an effort to allow flexibility. Part D sponsors are currently required to have systems established to receive and process fraud hotline tips. Therefore, we believe many Part D sponsors have the experience with using "other communications" which could include information such as supporting documentation submitted with the tip that may be used to support a complaint or document potential fraud.

Comment: Another commenter urged that CMS ensure tips are verified before they are used to suspend a provider or prescriber.

Response: The definition proposed does include language to state that a fraud hotline tip must be verified by further evidence. As mentioned in the proposed regulation the definition is

intended to be broad in an effort to allow flexibility since many plan sponsors have a fraud hotline and systems established for receiving and verifying potential fraud.

Based on the comments received and our responses we are finalizing the provision as proposed without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

b. Reporting

(1) Vehicle for Reporting

We stated that we planned to utilize a module within the HPMS as the program integrity portal for information collection and dissemination. We stated that the portal would serve as the core repository for the data addressed in sections 2008 and 6063 of the SUPPORT Act. We stated that the program integrity portal would not duplicate reporting requirements and is the only source that would be used to report and disseminate information as required in the final rule. Such data and the regular submission and dissemination of this important information would, in our view, strengthen CMS' ability to oversee plan sponsors' efforts to maintain an effective fraud, waste, and abuse program. We further believe that data sharing via use of a portal would, in conjunction with our proposals, help accomplish the following objectives in our efforts to alleviate the opioid epidemic:

- Enable CMS to perform data analysis to identify fraud schemes.
- Facilitate transparency among CMS and plan sponsors through the exchange of information.
- Provide better information and education to plan sponsors on potential fraud, waste, and abuse issues, thus enabling plan sponsors to investigate and take action based on such data.
- Improve fraud detection across the Medicare program, accordingly allowing for increased recovery of taxpayer funds and enrollee expenditures (for example, premiums, co-insurance, other plan cost sharing).
- Provide more effective support, including leads, to plan sponsors and law enforcement.

• Increase beneficiary safety through increased oversight measures.

We received a few comments on our planned reporting vehicle and our responses follow.

Comment: Several commenters noted reporting through a new HPMS module will create duplication of information and recommended that CMS institute one consistent reporting mechanism since plans can report directly to the MEDIC or into the HPMS, allow greater access to expedite reporting and provide further clarification where Part D sponsors should report.

Response: The program integrity portal will not duplicate reporting requirements and is the only source that will be used to report and disseminate information as required in the final rule.

Comment: A commenter inquired about the difference between the new portal and existing HPMS module and also questioned how plans will be assured that CMS will investigate the allegations submitted.

Response: The current Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE-FWA) module in HPMS will continue to serve as a repository for data projects that plan sponsors currently use as leads and a resource in conducting oversight of their fraud detection and prevention efforts. The new program integrity portal in HPMS will be the primary source for plan sponsors to submit information related to the inappropriate prescribing of opioids, payment suspensions of Part D pharmacies, and referral of substantiated or suspicious activities of a provider of services or supplier related to fraud, waste, and abuse.

(2) Type of Data to Be Reported by Plans

Sections 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), as noted, state that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs, respectively, to CMS or its designee. To conform to the aforementioned requirements of sections 2008(a) and (b) and section 6063(b) of the SUPPORT Act, we proposed to add new regulatory language, effective beginning in 2021, in parts 422 and 423 as stated throughout this section.

First, we proposed new language at §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to include the new provisions. The new §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would state that the MA organization or Part D plan sponsor, respectively, must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

- Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and
- Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

Second, the new §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) would require the data referenced in proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to be submitted via the program integrity portal. We proposed that MA organizations and Part D plan sponsors would have to submit the data elements, specified later in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by plan sponsors; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

- Date of Referral
- Part C or Part D Issue
- Complainant Name.

- Complainant Phone.
- Complainant Fax.
- Complainant Email.
- Complainant Organization Name.
- Complainant Address.
- Complainant City.
- Complainant State.
- Complainant Zip.
- Plan Name/Contract Number.
- Plan Tracking Number.
- Parent Organization.
- Pharmacy Benefit Manager.
- Beneficiary Name.
- Beneficiary Phone.
- Beneficiary Health Insurance Claim Number (HICN)
- Beneficiary Medicare Beneficiary Identifier (MBI).
- Beneficiary Address.
- Beneficiary City.
- Beneficiary State.
- Beneficiary Zip.
- Beneficiary Date of Birth (DOB).
- Beneficiary Primary language.
- Beneficiary requires Special Accommodations. If Yes, Describe.
- Beneficiary Medicare Plan Name.
- Beneficiary Member ID Number.
- Whether the Beneficiary is a Subject.

- Did the complainant contact the beneficiary? If Yes, is there a Report of the Contact?
- Subject Name.
- Subject Tax Identification Number (TIN).
- Does the Subject have Multiple TIN's? If Yes, provide.
- Subject NPI.
- Subject DEA Number.
- Subject Medicare Provider Number.
- Subject Business.
- Subject Phone Number.
- Subject Address.
- Subject City.
- Subject State.
- Subject Zip.
- Subject Business or Specialty Description.
- Secondary Subject Name.
- Secondary Subject Tax Identification Number (TIN)
- Does the Secondary Subject have Multiple TIN's? If Yes, provide.
- Secondary Subject NPI.
- Secondary Subject DEA Number.
- Secondary Subject Medicare Provider Number.
- Secondary Subject Business.
- Secondary Subject Phone Number.
- Secondary Subject Address.
- Secondary Subject City.
- Secondary Subject State.
- Secondary Subject Zip.

- Secondary Subject Business or Specialty Description.
- Complaint Prior MEDIC Case Number.
- Period of Review.
- Complaint Potential Medicare Exposure.
- Whether Medical Records are Available.
- Whether Medical Records were Reviewed.
- Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
- What Law Enforcement Agency(ies) has it been Referred to.
- Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE-FWA) was Used.
- Whether the submission has indicated Patient Harm or Potential Patient Harm.
- Whether the submission has been Referred. If so, provide Date Accepted.
- What Agency was it Referred to.
- Description of Allegations/Plan Sponsor Findings.

We noted that the requirement for reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies under new § 422.503(b)(4)(vi)(G)(*4*) would only apply to Medicare Part C in the context of Medicare Advantage Prescription Drug Plans (MA-PD plans). We stated our belief that this information is necessary to enable CMS to fully and completely understand the identity of the applicable party, the specific behavior involved, and the status of the action. We solicited public comment on these requirements.

We received several comments on the ability to impose payment suspensions on pharmacies and our responses to those comments follow.

Comment: A commenter supported CMS' implementation of the SUPPORT Act language that a fraud hotline tip, without further evidence, is not a credible fraud allegation for

payment suspension purposes. However, the commenter was concerned that CMS did not include what guidelines should be taken into consideration for procedures and data collection.

Response: We appreciate the commenter's support. However, many plan sponsors currently implement payment suspensions based on credible allegations of fraud and other reasons that may be contractual in nature. We believe that plan sponsors have established procedures and data collection based on their existing internal policies and procedures and as part of their fraud, waste and abuse oversight and monitoring efforts. The data will be reported through a program integrity portal that is discussed further later in this regulation.

Comment: Commenters requested that CMS further clarify the definition of a payment suspension, such as what entities are subject to payment suspensions, whether payment suspensions are applicable to physicians, and the applicable standards and responsible parties for making determinations.

Response: We believe the proposed regulation is clear in defining that a Part D pharmacy payment suspension based on credible allegation of fraud is applicable to Part D pharmacies. Additionally, we believe the proposed regulation is clear in stating that Part D plan sponsors are responsible for determining if a payment suspension should be implemented. Part D plan sponsors currently impose payment suspensions for other reasons that may be contractual in nature. Part D plan sponsors are responsible for oversight of their contracted entities, such as pharmacy benefit managers (PBMs) and pharmacies, and have established policies and procedures in their contractual arrangements.

Comment: A commenter recommended that CMS consider a targeted approach to payment suspensions, which would include pharmacy claim adjudications suspensions that would allow non-problematic claims from suspected pharmacies to be processed and paid. Another commenter questioned if CMS will have a process to reverse or deny payments.

Response: Part D plan sponsors and MA-PD plans have the authority to impose payment suspensions based on a credible allegation of fraud. However, Part D plan sponsors and

MA-PD plans also may consider a targeted approach to payment suspensions pursuant to contractual agreements. Part D plan sponsors and MA-PD plans are responsible for oversight of their contracted entities, such as PBMs and pharmacies, and have established policies and procedures in their contractual arrangements.

Comment: A commenter opposed CMS' proposal to suspend payments to fee-for-service (FFS) providers and suppliers pending a credible allegation of fraud, given that patients and providers can be at risk for an uncertain amount of time. The commenter also opposed the definition for credible allegation of fraud based on the need to establish clear guidance on how long a payment suspension will last and the concern that LTC's will be financially liable.

Response: We appreciate this feedback; however, although we proposed a modification to the reference to fraud hotline complains in 42 CFR 405.370, our proposal did not discuss payment suspensions for fee-for-service providers generally. Instead, the scope of this rule is limited to payment suspensions imposed on pharmacies by Part D plan sponsors. Part D plan sponsors currently conduct pharmacy payment suspensions based on credible allegations of fraud. This final rule is requiring Part D plan sponsors to report to CMS any pharmacy payment suspensions based on credible allegations of fraud through a website portal. The length of a payment suspension may vary based on the situation and the plan sponsors own business agreements.

Comment: We received a couple of comments regarding how the reporting of payment suspensions may interfere or preempt state-level requirements regarding payment to pharmacies.

Response: We have contractual agreements with the Part D plan sponsors and do not oversee contractual relationships between a plan sponsor, PBM and participating pharmacies. Part D Plan sponsors already have the authority to implement payment suspensions for pharmacies based on credible allegations of fraud. However, Section 2008 of the SUPPORT Act requires Part D plan sponsors to report those payment suspensions to the Secretary.

The requirement for Part D plan sponsors to report pharmacy payment suspensions based on credible allegations of fraud does not replace state law and this new federal requirement will not affect existing state statutes and regulations. We believe addressing specific state statutes and regulations are outside the scope of this regulation.

Comment: We received several comments expressing concerns with ensuring pharmacies have due process rights, an appeals process and advance notice prior to implementing a payment suspension. One commenter opposed this proposed regulation because it lacks fundamental due process protections for pharmacies. Another commenter noted that pharmacies should not be subject to payment suspension without greater certainty of fraud. Additionally, the commenter noted that pharmacies should receive advance notice of potential allegations of fraud and afforded an expeditious appeals process prior to any payment suspension. Commenters also noted that payment suspensions should not occur until there is legal evidence and also requested that CMS provide guidance on ensuring that plan actions against pharmacies are fully grounded with evidence and provides pharmacies the ability to quickly address complaints and prevent suspension of payment.

Response: Section 2008 authorizes Part D sponsors and MA-PD plans to suspend payments based on a credible allegation of fraud. Part D plan sponsors and MA-PD plans may currently impose payment suspensions for other reasons that may be contractual in nature. We have clarified the definition for credible allegation of fraud, fraud hotline tip, and substantiated and suspicious activities of fraud, waste and abuse. We decline to accept the recommendation because Part D plan sponsors and MA-PD plans are responsible for oversight of their contracted entities, such as PBMs and pharmacies and have established policies and procedures in their contractual arrangements.

We received a few comments on the data elements to be submitted by plans and our responses follow.

Comment: A commenter recommended that CMS allow flexibility in submitting data elements and allow Part D sponsors to enter "blank" fields if certain information is not available and not restrict the number of users. Commenter also recommended that information provided to Part D sponsors from the website portal be used for informational purposes only. However, if action is required on behalf of the Part D sponsors, then CMS should clearly specify.

Response: In response to the comment, we are clarifying that plan sponsors will be provided reporting flexibility within the portal when information is not available or not relevant to the referral being reported. The comment also allowed us the opportunity to re-evaluate the level of detail that we were requiring in the regulatory text for the data reported. We are modifying the regulatory text to reflect broad categories of information that will be collected rather than individual data elements. The data categories, as applicable, include referral information and actions taken by the plan sponsor on the referral.

Examples of the types of data to be collected in these categories include, but are not limited to, identifying information on the complainant, beneficiary, and subject of the referral, description of the referral (that is, services not rendered, prescriptions billed but the beneficiary never received, and identity theft), and any actions taken (that is, conducted an audit of the provider, referred the provider to the IMEDIC or Law Enforcement, or removed a provider from their network). The categories of data that we are making final in the regulatory text will provide flexibility.

The commenter also inquired if action is required on behalf of the Part D sponsors based on information provided from the website portal. The quarterly reports we are sharing will assist plan sponsors with their monitoring and oversight efforts. These reports themselves are not a sufficient basis for a Medicare Part D plan sponsor to take action without conducting its own supporting analysis of specific data. We urge plan sponsors to confirm potential fraud waste and abuse through a reliance upon their own established protocols. Any actions taken as a result of the reports and the Sponsors follow-up activities should be reported through the website

portal. We also note, in response to the commenter, that plan sponsors will also have the ability to allow access to multiple users.

Comment: Commenters also requested that CMS clarify why the required data elements list both the HICN and the MBI. Commenters also requested clarification who should the reporting be submitted to and the method that should be utilized.

Response: In response to the comment, we are clarifying that only the MBI will be utilized, as part of the broad category of referral information, to ensure that the beneficiary's information is captured appropriately. Plan sponsors will be required to report information through the program integrity portal in HPMS.

Based on the comments received and our responses we are modifying the regulatory text regarding the data to be reported. The final regulation text reflects the broad categories of data that CMS will employ in the construction of the data that will be required for plans to submit to the program integrity portal. In addition, the applicability date for plan sponsor reporting will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(3) Timing of Plan Sponsor's reporting

We proposed in new §§ 422.503(b)(4)(vi)(G)(*6*)(*i*) and 423.504(b)(4)(vi)(G)(*6*)(*i*) MA organizations and Part D plan sponsors would be required to notify the Secretary, or its designee of a payment suspension described in §§ 422.503(b)(4)(vi)(G)(*4*)(*i*) and 423.504(b)(4)(vi)(G)(*4*)(*i*) 14 days prior to implementation of the payment suspension. This timeframe will allow us to provide our law enforcement partners sufficient notice of a payment suspension to be implemented that may impact an ongoing investigation into the subject. We proposed that §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*) plans would be required to submit the information described in §§ 422.503(b)(4)(vi)(G)(*4*)(*ii*) and 423.504(b)(4)(vi)(G)(*4*)(*ii*) no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1

through March 31, April 1 through June 30, and July 1 through September 30. We proposed that plans would be required to submit information beginning in 2021. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1 - December 31). We believe that quarterly updates would be frequent enough to ensure that the portal contains accurate and recent data while giving plans sufficient time to furnish questioned information. We solicited public comment on the timing of reporting by plans

We received several comments on the timing of reporting by plans and our responses to those comments follow.

Comment: We received numerous comments regarding the 14-day advance notice to CMS for payment suspensions. Most commenters are concerned that this gives the bad actors too much time to continue the fraudulent activity which could result in millions of dollars lost, prevent overutilization of services and more importantly, beneficiary harm. A commenter suggested a 72-hour wait period instead of 14 days. Another commenter recommended allowing plans 72 hours to notify CMS after the suspension rather than 14 days prior to the suspension. One commenter recommended immediate payment suspension of pharmacies and then provide referral within 14 days to CMS. Another commenter mentioned that allowing plans to submit payment suspension immediately and provide an update monthly will reduce burden for plans sponsors and PBMs. Another commenter recommended CMS provide a list of providers for plans to review prior to initiation of a payment suspension which would require plans to notify the agency within 14 days prior to implementing. Additionally, if providers are not included in the notification plans would notify the agency within 5-10 days of the payment suspension which would align with many Medicaid state guidelines. Commenters also expressed confusion regarding whether plans were being prohibited from suspending immediately. Another commenter recommended removal of a suspension if it is determined that there is no good cause.

Response: Based on comments received requesting a reduced timeframe for advance notice of imposing payment suspensions and balancing that with concerns raised by our federal law enforcement partners to ensure deconfliction, we will finalize the provision with a 7-day advance notice requirement with a limited exception. The advance notice provides collaboration and necessary deconfliction with law enforcement but also allows an exception for instances where more immediate payment suspension is warranted. For example, the exception would allow for immediate suspension when a plan has concerns regarding a credible allegation of fraud which may involve potential patient harm.

Comment: Commenters also recommended that CMS allow exceptions from the proposed quarterly reporting when disclosure may jeopardize an ongoing investigation. Commenters also requested that CMS extend reporting to 30 days of the close of the quarter versus the proposed 15 days to allow data gathering and quality assurance before the report submission.

Response: Based on the comments received we will modify the proposed provision to extend the reporting timeframe for plan sponsors to 30 days after the close of the quarter. We will not modify to allow exceptions to the reporting requirement. Based on the comments received and our responses in this section we are finalizing the following two policies with modification.

- We will require a 7-day advance notice with exemptions in certain cases, such as potential for beneficiary harm.

- We will adjust the timeline for submission to 30 days after the close of the quarter. The applicability date for plan sponsor reporting has been postponed until January 1, 2022.

(4) Requirements and Timing of CMS' Reports

As mentioned earlier in this final rule, section 6063(a) of the SUPPORT Act requires the Secretary make available to the plans, not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include

administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Moreover, the information must be anonymized data submitted by plans without identifying the source of such information.

Section 6063 of the SUPPORT Act requires the Secretary provide reports no less frequently than quarterly. Consistent with this requirement, we proposed in the new §§ 422.503(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) and 423.504(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) that we will provide MA organizations and Part D plan sponsors with data report(s) or links to data no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We proposed to provide this information beginning in 2021. For the first quarterly report (April 15, 2021), the report will reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021. Similar to the timing requirements related to new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*), we believe that quarterly updates would strike a suitable balance between the need for frequently updated information while giving us time to review and analyze this data in preparation for complying with new §§ 422.503(b)(4)(vi)(G)(*4*) through (*7*) and 423.504(b)(4)(vi)(G)(*4*) through (*7*). We solicited public comment on the timing of CMS dissemination of reports to plans.

We received no comments on this proposal and therefore are finalizing this provision without modification; however, the applicability date for the quarterly reports will be for plan years beginning on or after January 1, 2022 for reasons previously discussed.

IV. Enhancements to the Part C and D Programs

A. Out-of-Network Telehealth at Plan Option

On April 16, 2019, CMS finalized requirements for MA plans offering additional telehealth benefits (ATBs).[28] Section 50323 of the BBA of 2018 created a new subsection (m) of section 1852 of the Act, authorizing MA plans to offer ATBs to enrollees starting in plan year 2020 and treat ATBs as basic benefits. In the April 2019 final rule, we finalized a new regulation at § 422.135 to implement that authority. As part of the parameters for the provision of ATBs, we finalized a requirement, at § 422.135(d), that MA plans furnishing ATBs only do so using contracted providers, and § 422.135 specifically provides that benefits furnished by a non-contracted provider through electronic exchange (defined in the regulation) may only be covered by an MA plan as a supplemental benefit.

In the February 2020 proposed rule, we solicited comment on whether § 422.135(d) should be revised to allow all MA plan types, including PPOs, to offer ATBs through non-contracted providers and treat them as basic benefits under MA.

We received many responses to this request for comment. We thank the commenters for the time and effort that went into developing these detailed responses and feedback for CMS. We will carefully review and consider all input received from stakeholders as we determine whether to revise § 422.135(d) to allow MA plans to offer ATBs through non-contracted providers. At this time, we are not revising any requirements at § 422.135, and any revisions regarding ATBs will be proposed through future notice and comment rulemaking.

B. Supplemental Benefits, Including Reductions in Cost Sharing (§ 422.102)

In the Medicare Program; Establishment of the Medicare Advantage Program Final Rule, published in the **Federal Register** on January 28, 2005 (hereinafter referred to as the January 2005 MA final rule) (70 FR 4588, 4617), CMS established that an MA plan could reduce cost

[28] https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare

sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act only as a mandatory supplemental benefit and codified that policy at § 422.102(a)(4). In order to clarify the scope of section 1854(e)(4)(A) of the Act, we proposed in the February 2020 proposed rule to amend § 422.102(a)(4) and add new rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to further clarify the different circumstances in which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit; we also proposed to specifically authorize certain flexibility in the mechanisms by which an MA plan may make reductions in cost sharing available.

Currently, reductions in cost sharing are an allowable supplemental benefit in the MA program and may include:

• Reductions in the cost-sharing for Parts A and B benefits compared to the actuarially equivalent package of Parts A and B benefits; and

• Reductions in cost-sharing for Part C supplemental benefits, for example provided for specific services for enrollees that meet specific medical criteria, such that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits.

We proposed to codify regulation text to clarify that reductions in cost sharing for both (1) Part A and B benefits and (2) covered items and services that are not basic benefits are allowable supplemental benefits but may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). We proposed to revise the current language at § 422.102(a)(4) by inserting the phrase "for Part A and B benefits" after the cite to section 1854(e)(4)(A) of the Act, and to add a new paragraph (a)(5) to specify that reduced cost sharing may be applied to items and services that are not basic benefits. Under our proposal, the reductions in cost sharing for both categories may only be provided as a mandatory supplemental benefit.

We explained in the proposed rule that MA plans may currently choose to structure mandatory supplemental benefits that are in the form of cost sharing reductions in a few ways.

For example, the current rules permit MA plans to offer, as a supplemental benefit, a manual reimbursement process or use of a debit card to reduce cost sharing towards plan covered services or to provide coverage of 100 percent of the cost of covered items. MA plans may also decide to offer, as a supplemental benefit, a reduction in enrollee's costs through a maximum allowance. An MA plan may establish a dollar amount of coverage that may be used to reduce cost sharing towards plan covered services and subject to a plan-established annual limit; enrollees can "spend" the allowance on cost sharing for whichever covered benefits the enrollee chooses. In both scenarios, MA plans are expected to administer the benefit in a manner that ensures the debit card and/or allowance can only be used towards plan-covered services. We proposed to codify these flexibilities in how reductions in cost sharing are offered at § 422.102(a)(6)(i) and (ii). We clarified in the proposed rule that these flexibilities are only for Part C supplemental benefits, as defined in § 422.100(c) and discussed in section VI.F. of the proposed rule (and section V.E. of this final rule) and that cost sharing for Part D drugs is not included in these flexibilities.

As proposed, the flexibilities identified would be permitted only as a mandatory supplemental benefit, which is why we proposed to codify them in § 422.102(a). Further, we explained that the flexibility was only for items and services that are identified in the MA plan's bid and marketing and communication materials as covered benefits and proposed the regulation text using the terms "covered benefits" and "coverage of items and services" to make that clear. Under our proposal and consistent with current guidance in Chapter 4 of the Medicare Managed Care Manual, § 40.3 (allowing debit cards to be used for plan-covered over-the-counter (OTC) items under the conditions that the card is exclusively linked to the OTC covered items and has a dollar limit tied to the benefit maximum), MA plans would not be able to offer use of a debit card for purchase of items or services that are not covered. We stated that a debit card could be utilized as a reimbursement mechanism or as a means for the MA plan to make its payment for an item or service; in either case, the use of the card would have to be tied to coverage of the

benefit. Like all other MA coverage, the flexibilities we proposed would be limited to the specific plan year and we clarified that this authority to use debit cards or a basket of benefits up to a set value from which an enrollee can choose cannot be rolled over into subsequent years. We proposed specific text in paragraph (a)(6) limiting these forms of supplemental benefits to the specific plan year to emphasize that rolling over benefits to the following plan year is not permitted.

We explained in the proposed rule that for both benefit options, MA plans would have the flexibility to establish a maximum plan benefit coverage amount for supplemental benefits or a combined amount that includes multiple supplemental benefits, such as a combined maximum plan benefit coverage amount that applies to dental and vision benefits. We reiterated that plans may not offer reimbursement, including through use of a debit card, to pay for items and services that are not covered by the plan and that reductions in cost sharing as a supplemental benefit are subject to an annual limit that the enrollee can "spend" on cost sharing for whichever *covered benefits* the enrollee chooses. Under our proposal, MA plans could use a receipt-based reimbursement system or provide the dollar amount on a debit card (linked to an appropriate merchant and item/service codes) so that the enrollee may pay the cost sharing at the point of service. Our proposal was to codify and clarify existing guidance and practices and we stated that it was not expected to have additional impact above current operating expenses. We also stated that the proposal would not impose any new collection of information requirements.

We thank commenters for helping inform CMS' Reductions in Cost Sharing policy. We received 11 comments on this proposal; we summarize them and our responses follow:

Comment: Many comments were supportive of this proposal.

Response: We thank commenters for their feedback.

Comment: A commenter suggested CMS confirm that plans may implement allowances as a multi-year benefit.

Response: We cannot confirm this and it would not be permitted. As proposed and finalized, the changes adopted here are for benefits offered in each plan year and cannot be rolled over or spread across multiple plan years. This is necessary for a number of reasons. CMS only has one-year contracts with MAOs; as such, there is no guarantee that a particular plan will continue into the following year. Additionally, there is also no guarantee an enrollee will remain in a plan from year to year as an enrollee has the option to change plans each year. Further, and more importantly, bids must be submitted by MA organizations each year, showing the revenue requirements for furnishing benefits for the contract year; bids are compared to benchmarks that are set each year and used to determine the amount of beneficiary rebates under § 422.266. Under § 422.266, these rebates may be used to pay the premium for the supplemental benefits described in § 422.102(a)(6) or to buy down Part B or Part D premiums; use of the beneficiary rebate for payment of a premium for supplemental benefits in a different plan year is not permitted and would be inconsistent with the statutory requirement in section 1854(b)(1)(C) of the Act that MA plans provide the rebate to enrollees for the applicable year. It is not consistent with our regulations on bidding (§§ 422.250 through 422.266) for an MA plan to have a multi-year benefit.

Comment: A commenter suggested CMS allow plans to offer reductions in cost sharing for items and services that are not covered. This commenter also suggested CMS not subject reductions to cost sharing or allowances to an annual limit.

Response: In order to have a reduction in cost sharing, there has to be a covered benefit. We allow plans to have a debit card to cover cost sharing but they must identify the benefits as covered either in the plan benefit package (PBP) category or notes in the bid. Consistent with this, all the items and services for which payment may be made (in the form of a reduction in cost sharing that would otherwise apply for the item or service or in the form of the MA plan's payment of its share of the amount owed to the provider) must meet the requirements to be a supplemental benefit. These requirements are discussed in section V.C. of

this final rule regarding our proposal to amend § 422.100(c)(2) to codify the requirements for supplemental benefits.

Comment: A commenter requested CMS provide additional guidance on how plans can make sure that supplemental benefits furnished in the form of an allowance meet the "primarily health related" requirement as enrollees typically have discretion in how they use these allowance-based dollars.

Response: The MA plan must ensure that its coverage, whether through reimbursement or direct payment, of items and services is consistent with the rules for supplemental benefits. The flexibility provided in this allowance benefit to permit the enrollee to choose among covered benefits does not change the rules for what may be covered. For an MA plan that uses a receipt-based reimbursement method of administering this allowance benefit, the MA plan must ensure that the receipts support a determination that reimbursement is being provided only for items and services that are covered supplemental benefits. We understand that debit and stored value cards can be programmed to permit their use only for purchase of specific items and services and at certain locations, such as cost sharing payments at a physician's office or payment for primarily health-related items such as bandages at a pharmacy. If an MA organization is unable to limit use of a debit or stored value card to the appropriate providers and covered benefits (such as through programming limits to certain merchant codes or inventory information approval system codes) to ensure compliance with §§ 422.100(c)(2) and 422.102(a), use of a debit or stored value card as a means of reimbursing or providing reductions in cost sharing may not be appropriate by that MA organization. We note that the Internal Revenue Service has provided guidance on how debit and stored value cards are permitted in connection with health savings accounts and flexible spending accounts when the cards are capable of being limited to qualified expenses; see, for example: Revenue Ruling 2003-43, 2003-21 I.R.B. 935, available at IRS.gov/pub/irs-drop/rr-03-43.pdf. We also clarify here that use of a stored value or debit card is not the covered

supplemental benefit; such cards are only a means by which the MA plan makes direct payment to the provider for or reimbursement to the enrollee for the covered items and services.

The covered items and services that are paid or reimbursed this way must meet the requirements and standards to be supplemental benefits (or to be basic benefits in the case of reducing the cost sharing for a Part A or B covered benefit). Related to this, we reiterate that that payment of or reimbursement of cost sharing for Part D benefits by an MA plan is not a permissible supplemental benefit. To clarify this, we are finalizing § 422.102(a)(5) with additional text that Part D cost sharing may not be reduced or paid as a Part C supplemental benefit. MA plans may, under § 422.266, use rebates to pay the premiums for Part D benefits, including the premiums for supplemental drug coverage described at §423.104(f)(1)(ii). For more information on the types of items and services that may be covered by an MA plan as a supplemental benefit, we direct readers to the April 27, 2018 memo titled "Reinterpretation of "Primarily Health Related" for Supplemental Benefits" and section V.C of this rule, which codifies those requirements for details.

Comment: A commenter expressed concern about potential limits on these benefits and the idea that financial need must be proven in order to allow access.

Response: Reduced cost sharing as a supplemental benefit must follow the requirements concerning supplemental benefits, which include uniformity requirements § 422.100(d) discussed in section V.C of this final rule. That is, if a plan chooses to offer reduced cost sharing as a supplemental benefit, it must be offered uniformly to plan enrollees. MA plans may not offer supplemental benefits based on financial need. Because of the unique nature of Special Supplemental Benefits for the Chronically Ill (SSBCI) and the statutory authority for those benefits to not be primarily health related, the recently adopted rule at § 422.102(f)(2)(iii) permits an MA plan to consider social determinants of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. (85 FR

33801, 33804) However, MA plans may not use social determinants, such as financial need, as the sole basis for determining eligibility for SSBCI.

Comment: A commenter mentioned that while stated in the preamble, CMS did not include specific regulation text stating that reduced cost sharing for basic benefits, specifically as it relates to the value of Part A and B benefits, is permitted.

Response: In the proposed rule, we included amendatory instructions to clarify that reductions in cost sharing for Part A and B benefits may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). Specifically, CMS proposed to revise the current language at § 422.102(a)(4) by inserting the phrase "for Part A and B benefits". (85 FR 9213) Thus, specific regulation text clarifying that reduced cost sharing for basic benefits, specifically for Part A and B benefits, is permitted as a supplemental benefit was included in the proposed language. We are finalizing this language.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to § 422.102(a)(4) and (a)(6)(i) and (ii) as proposed and are adding language to § 422.102(a)(5) further clarifying that cost sharing for Part D drugs is not included in these flexibilities.

C. Referral/Finder's Fees (§§ 422.2274 and 423.2274)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, published in the **Federal Register** on May 23, 2014 (79 FR 29960) (the May 2014 final rule), CMS codified rules in §§ 422.2274(h) and 423.2274(h) for MA organizations and Part D sponsors to pay agents and brokers for referrals of beneficiaries for enrollment in MA and Part D plans, also known as finder's fees. Currently, under §§ 422.2274(h) and 423.2274(h), CMS sets a referral fee limit that reflects an amount CMS determined is reasonably expected to provide financial incentive for an agent or broker to refer a beneficiary for an enrollment into a plan that is not the most appropriate to meet his or her needs. This is consistent with sections 1851(j)(2)

and 1860D-1(*l*) of the Act, which direct that the Secretary set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs. In an HPMS memo dated May 29, 2020, CMS limited referral fees to $100 for MA plans and $25 for PDP plans. Since referral fees are part of the definition of the term compensation in §§ 422.2274 and 423.2274, organizations may not pay independent agents more than the regulatory limits; CMS regulates referral fees as part of CMS's regulations on the compensation paid by the plan to an agent/broker for an enrollment, even if referral fees are paid separately from commissions or compensation for completed enrollments. CMS explained in the February 2020 proposed rule that because referral fees are already incorporated into compensation, limiting the amount of a referral fee does not impact the statutory requirement that CMS guidelines for compensation to an agent or broke incentivize the agent or broker enrolling a beneficiary in the plan that best meets their health care needs. CMS also explained in the proposed rule that for captive and employed agents and brokers, who only sell coverage for one organization, referral fees would not have any impact on how much the captive or employed agent is himself or herself paid.

Therefore, CMS proposed to remove §§ 422.2274(h) and 423.2274(h) and thereby eliminate the specific limitation on the amount a referral or finder fee paid by a plan to an agent or broker. CMS explained generally how the current regulation treats compensation as background for our proposal. As currently codified at §§ 422.2274(b) and 423.2274(b), compensation for initial enrollments may not exceed the fair market value and compensation for renewal enrollments may not exceed 50 percent of the fair market value. Compensation is defined in the same current regulation, at paragraph (a), as all monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes or awards, and referral or finder fees. By eliminating the individual referral fee limit, our proposal would restructure the regulation to only provide a limit on referral fees within the overall limit of Fair Market Value (FMV) that applies to all

compensation. CMS proposed to clarify that MA organizations and Part D sponsors have the ability to compensate agents for referrals, provided that the total dollar amount does not exceed FMV. CMS explained that the primary value for this proposed additional flexibility would be in connection with independent agents, as CMS believes that for captive and employed agents, referral/finder fees do not play a factor in making sure the agent enrolls the beneficiary in the best plan, since captive and employed agents only sell for one organization. CMS therefore proposed to eliminate the current specific limit on finder or referral fees that is codified at paragraph (h). CMS also explained that because the definition of compensation already includes referral or finder fees (which CMS did not propose to change), the result of this specific proposal would be an overall limit on compensation for initial and renewal enrollments that would include finder or referral fees. In section VI.H. of the proposed rule, CMS proposed additional changes for §§ 422.2274(g) and 423.2274(g) regarding agent and broker compensation for Part C and Part D enrollments; and under those proposals, the definition of compensation would continue to include finder or referral fees. As a result, the limits on overall compensation continued to include finder or referral fees under the proposed rule. CMS solicited comment on whether removing the limit on referral/finder's fees would generate concerns such as those discussed in the 2010 Call Letter for MA organizations issued March 30, 2009; CMS's October 19, 2011, memo entitled "Excessive Referral Fees for Enrollments;" or the May 2014 final rule that codified the referral/finder's fees limits in regulation. As background, these concerns included marketing practices designed to circumvent compensation limitations.

The comments CMS received on this specific proposal regarding referral/finders' fees and our responses to them follow.

Comment: Several commenters stated that referrals and enrollments are different activities and therefore, CMS should consider payment for these activities separately. The commenters pointed out that referrals are used to generate sales leads, that not all leads result in an enrollment, and when a lead does result in enrollment, referral and finder's fees are typically

not paid to the individual completing the sale. Some commenters pointed out that referral fees are not always provided to individuals as part of the compensation they are paid for an enrollment. The commenters suggested referral fees be removed from compensation and that a separate, reasonable limit be placed on referral fees. A commenter pointed out that the removal of the limit on referral fees would result in larger, well-financed health plans paying brokers more for referrals and that this would cause smaller health plans to lose out on broker referrals.

Response: CMS agrees with the commenters that referral fees and compensation are different types of payments and that plans distinguish between referral fees for sales leads and compensation to agents and brokers for enrollments. We understand that referral fees are a distinct part of market practices which we have determined, based on comments, should not be modified. We also realize that our proposal to remove specific limits on referral fees may put plans that can pay higher referral fees at an advantage over other plans. Based on the issues identified through comments we are maintaining the status quo. As such, CMS is finalizing a separate limit on referral fees in §§ 422.2274(f) and 423.2274(f) and is codifying the dollar figures currently used as the limits for referral fees. The current sub-regulatory policy has in place a $25 referral fee limit for PDPs and a $100 referral fee limit for MA-PDs. The proposal was to remove the current limits since referral fees are part of compensation paid to an agent for an enrollment. However, commenters pointed out that referral fees are not always provided to individuals as part of the compensation they are paid for an enrollment. Therefore, we are finalizing a specific dollar limit on fees paid for a single referral, recommendation, provision (as in providing a lead), or other means of referring a beneficiary to an agent, broker or other entity for potential enrollment in a plan instead of finalizing our proposal.

Section 1851(j)(2)(D) of the Social Security Act requires CMS to establish limitations to ensure that the use of compensation creates incentives for the agent/broker to enroll a beneficiary in a plan that best meets their needs. CMS does not require referral fees to be contingent on a beneficiary being enrolled in a plan because referral fees are essentially

payments for sales leads. Plans may determine the circumstances as to when they pay referral fees (for example, based on whether the lead chooses to enroll in the plan), provided such payment is in accordance with the requirements in this final rule. Therefore, referral fees are a different type of payment than the payments that we regulate as compensation to an agent or broker for enrollment of a beneficiary in a plan. Based on this, CMS is finalizing changes to the definition of the term "compensation" (codified in §§ 422.2274(a) and 423.2274(a)) to remove referral or finder fees from the list of what compensation includes. As discussed in more detail in section V.E of this final rule, compensation as defined in paragraph (a) is regulated as payment that is based on enrollment in a plan. CMS is finalizing a new §§ 422.2274(f) and 423.2274(f) to provide that payments may be made to individuals for the referral, recommendation, provision, or other means of referring beneficiaries to an agent/broker or other entity for potential enrollment into a plan and that such payments may not exceed $100 for a referral into an MA or MA-PD plan and $25 for a referral into a standalone PDP.

Comment: A commenter requested more transparency into payment of both referral fees and renewal fees. The commenter also suggested that CMS eliminate the renewal compensation for agents, stating that 98 percent of beneficiaries remain in the same plan or make a plan change to a "like" plan (that is, a plan that is similar enough to the previous plan that it does not result in a change of the renewal payment status to the agent/broker). The commenter stated that the renewal compensation created an un-level playing field between community-based non-profit plans and national competitors.

Response: We believe that the commenter may be conflating referral fees and renewal compensation. Referral fees are paid by plans for sales leads while renewal compensation is paid by a plan to an agent or broker for enrollments. The dollar amount of the limit on referral fees under the current regulation was set by CMS in subregulatory guidance, applying the regulatory standard that referral fees not exceed an amount that could be reasonably expected to provide a financial incentive to enroll a beneficiary in a plan that is not appropriate to the beneficiary's

needs. Here, we are finalizing a specific dollar amount as the limit on referral fees: $100 for a referral into an MA or MA-PD plan and $25 for a referral into a PDP plan. Plans may pay an amount per referral that is less than this limit but must not pay more than this limit. By establishing a specific dollar limit for referral fees in regulation, CMS is creating a level playing field for all plans who pay referral fees according to this policy. CMS is not including any type of increase to the referral fees since referrals do not require the same type of effort or have the same requirements that are associated with compensation.

The limit on renewal compensation is 50 percent of the fair market value (FMV) set for initial enrollment year compensation, as provided in §§ 422.2274(b)(ii) and 423.2274(b)(ii) of the current regulations and in §§ 422.2274(d)(3) and 423.2274(d)(3) of this final rule. As defined in §§ 422.2274(a) and 423.2274(a) in this final rule, FMV is calculated each year by increasing the prior year's FMV dollar amount by the MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312. This provision permits a change each year in compensation to agents and brokers that aligns with the change in the growth of per capita costs. Agents provide valuable assistance to beneficiaries whether the beneficiary is enrolling into a plan for the first time or staying in their existing plan. Many beneficiaries depend on their agents to assist them in reviewing their choices each year and helping them make a determination on whether to remain in their existing plan or to move into a new plan. Renewal compensation provides an incentive to provide such assistance to enrollees and we believe such compensation is appropriate to limit under our statutory responsibility to regulate compensation for agents and brokers. In addition, permitting renewal compensation avoids providing an inadvertent and unintended incentive for agents and brokers to churn beneficiaries through new enrollments into different plans each year in order to generate stable income.

After consideration of the comments and for the reasons outlined in the proposed rule, we are finalizing the definition of "compensation" (§§ 422.2274(a) and 423.2274(a)) without

including referral and finder's fees and are finalizing a new paragraph (f) in §§ 422.2274 and 423.2274 to impose specific limits on the payment amount for referral and finder's fees for MA and Part D enrollments.

D. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codified a policy to adjust Star Ratings for disasters, and finalized some measure updates. In the June 2020 final rule, CMS finalized an increase in the weight of patient experience/complaints and access measures from 2 to 4 for the 2023 Star Ratings. To further increase the predictability and stability of the Star Ratings system, we also finalized our proposal to directly remove outliers through Tukey outlier deletion before applying the clustering methodology to calculate the cut points, but we delayed the application of Tukey outlier deletion until the 2022 measurement year which coincides with the 2024 Star Ratings. We also finalized the removal of the Rheumatoid Arthritis Management measure and updated the Part D Statin Use in Persons with Diabetes measure weighting category for the 2021 measurement year and the 2023 Star Ratings.

In the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule placed on display at the Office of the Federal Register website on March 31, 2020 (hereinafter referred to as the March 31st

COVID-19 IFC), CMS adopted a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID-19 pandemic. The changes adopted in the March 31st COVID-19 IFC addressed the need of health and drug plans and their providers to adapt their current care practices in light of the public health emergency (PHE) for COVID-19 and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. In addition to needing to address data collections scheduled for 2020 during the initial part of the PHE, we believe that there will be changes in measure-level scores because of increased healthcare utilization due to COVID-19, reduced or delayed non-COVID-19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID-19 inpatient utilization. We realize that this will impact the data collected during the 2020 measurement year which will impact the 2022 Part C and D Star Ratings. Thus, as part of the March 31st COVID-19 IFC, we made some adjustments to account for the potential decreases in measure-level scores so health and drug plans can have some degree of certainty knowing how the Star Ratings will be adjusted and can continue their focus on patients who are most in need right now.

Specifically, the March 31st COVID-19 IFC:

- Eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data otherwise collected in 2020 and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the PHE for COVID-19);
- Establishes how we would calculate or assign Star Ratings for 2021 in the event that CMS's functions had become focused on only continued performance of essential Agency functions and the Agency and/or its contractors did not have the ability to calculate the 2021 Star Ratings;

- Modifies the current rules for the 2021 Star Ratings to replace any measure that had a systemic data quality issue for all plans due to the COVID-19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- Replaces the measures calculated based on HOS data collections with earlier values that are not affected by the public health threats posed by COVID-19 for the 2022 Star Ratings in the event that we were unable to complete Health Outcomes Survey (HOS) data collection in 2020 (for the 2022 Star Ratings) due to the PHE for COVID-19;
- Removes guardrails (i.e., measure-specific caps on cut point changes from one year to the next) for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;
- Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and
- Revises the definition of "new MA plan" so that for purposes of 2022 QBPs based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings are based in part on data for the 2018 performance period.

Please see the March 31st COVID-19 IFC for further information on these changes for the 2021 and 2022 Star Ratings. In addition, the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule (CMS-3401-IFC) which appeared in the Federal Register on September 2, 2020 (hereinafter referred to as the September 2nd IFC), modifies application of the extreme and uncontrollable circumstances policy for the calculation of the 2022 Part C and D Star Ratings to address the PHE for COVID-19 to: (1) remove the 60 percent exclusion rule for cut point calculations for non-CAHPS measures; and (2) remove the 60 percent exclusion rule for the determination of the performance summary and variance thresholds for the Reward

Factor. These changes were made by amending the regulations at §§ 422.166(i)(11) and 423.186(i)(9).

In the February 2020 proposed rule, in addition to the policies addressed in the June 2020 final rule, we proposed to implement substantive updates to the specifications of the Health Outcomes Survey (HOS) outcome measures, add two new Part C measures to the Star Ratings program, clarify the rules around consolidations when data are missing due to data integrity concerns, and add several technical clarifications. We also proposed to codify additional existing rules for calculating MA Quality Bonus Payment (QBP) ratings. We proposed these changes to apply to the 2021 measurement period and the 2023 Star Ratings, but as discussed in this final rule, we are finalizing these policies from the proposed rule (that is, data would be collected and performance measured) for the 2022 measurement period and the 2024 Star Ratings.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the proposal and comments we received on each proposal and provide our responses.

2. Definitions (§ 422.252)

We proposed to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. Under our proposed changes, *New MA plan* would mean a plan that: (1) is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. In addition, we proposed to add text to the definition to explicitly explain that the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies.

Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent

organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard. For example, if a parent organization is listed for an MA contract in April 2019, and that parent organization does not have any other MA contracts at any point during April 2017 – April 2019, the plans under the MA contract would be considered new MA plans for 2020 QBP purposes.

We received no comments on the proposed amended definition in § 422.252 for a new MA plan and are finalizing the policy as proposed for the reasons outlined in the proposed rule and this final rule. However, we are not finalizing the last sentence included in the proposed regulation text because the proposed regulation text mistakenly included a sentence repeating how we would identify parent organizations in April of the calendar year before the payment year[29]. Although we are finalizing this provision as applicable beginning January 1, 2022, we reiterate that it codifies current policies that have been in place since 2012 (76 FR 21486). In addition, we note that the regulation text finalized here includes the language adopted in the March 31st COVID-19 IFC (CMS-1744-IFC) to govern how the definition is applied for 2021 Star Ratings (85 FR 19290).

3. Contract Consolidations (§§ 422.162(b)(3)(iv), 422.164(g)(1)(iii)(A), 423.182(b)(3)(ii), and 423.184(g)(1)(ii)(A))

The process for calculating the measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). We proposed to add a rule to account for instances when the measure score is missing from the consumed or surviving contract(s) due to a data integrity issue as described at §§ 422.164(g)(1)(i) and (ii) and 423.184(g)(1)(i) and (ii). CMS proposed to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. We proposed that these rules would apply for contract

[29] The following sentence is excluded from the regulatory text: Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard.

consolidations approved on or after January 1, 2021. First, we proposed minor technical changes to the regulation text in §§ 422.162(b)(3)(iv)(A) and (B) and 423.182(b)(3)(ii)(A) and (B) to improve the clarity of the regulation text. Second, we proposed to redesignate the current regulation text (with the technical changes) as new paragraphs (b)(3)(iv)(A)(*1*) and (b)(3)(iv)(B)(*1*) and (b)(3)(ii)(A)(*1*) and (b)(3)(ii)(B)(*1*) of these regulations and to codify this new rule for contract consolidations approved on or after January 1, 2021 as §§ 422.162(b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) and 423.182(b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*). We also proposed an additional rule at §§ 422.164(g)(1)(iii)(A) and 423.184(g)(1)(iii)(A) to address how the Timeliness Monitoring Project (TMP) or audit data are handled when two or more contracts consolidate. We proposed that the TMP or audit data will be combined for the consumed and surviving contracts before carrying out the methodology as provided in paragraphs B through N (for Part C) and paragraphs B through L (for Part D). We proposed that these rules would apply for contract consolidations approved on or after January 1, 2021 and the proposed regulation text included language to that effect. We proposed to redesignate the current regulation text as new paragraphs (g)(1)(iii)(A)(*1*) and (g)(1)(ii)(A)(*1*) of these regulations and to codify this new rule for contract consolidations on or after January 1, 2021 as paragraphs (g)(1)(iii)(A)(*2*) and (g)(1)(ii)(A)(*2*).

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Commenters supported the proposals related to how to calculate scores when either the surviving or the consumed contract has a measure-level data integrity issue. A commenter recommended in these instances that the preview reports should include the combined TMP data for contracts that consolidate.

Response: We appreciate these comments and will be combining the TMP data in preview reports for the surviving and consumed contracts.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the changes as proposed to §§ 422.162(b)(3)(iv), 422.164(g)(1)(iii)(A), 423.182(b)(3)(ii), and 423.184(g)(1)(ii)(A) with a revision to the applicable date. Given the timing of the finalization of this rule, we are finalizing the provisions as applying to contract consolidations that are approved on or after January 1, 2022.

4. Adding and Updating Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Star Ratings program. As discussed in the April 2018 final rule, due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance document with publication of the Star Ratings. In the February 2020 proposed rule, CMS proposed measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2021.

a. Proposed Measure Updates - Updates to the Improving or Maintaining Physical Health Measure and Improving or Maintaining Mental Health Measure from the HOS (Part C).

In accordance with § 422.164(d)(2), we proposed substantive updates to two measures from the Medicare Health Outcomes Survey (HOS): the Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure.

First, we proposed to change the case-mix adjustment (CMA) for these measures. Case-mix adjustment is critical to measuring and comparing longitudinal changes in the physical and mental health of beneficiaries across MA contracts. To ensure fair and comparable contract-level scores, it is important to account for differences in beneficiary characteristics across contracts for these two measures. CMS proposed to modify the current approach used for adjusting for

differences in the case-mix of enrollees across contracts for these two measures. The proposed approach would improve the case-mix model performance and simplify the implementation and interpretation of case-mix results when particular case-mix variables, such as household income, are missing. The current method for handling missing case-mix variables results in a reduced number of case-mix variables used for a beneficiary because it does not use any of the case-mix variables in a group of adjusters if one is missing from the group (see 2021 Medicare Part C & D Star Ratings Technical Notes Attachment A for a full description of the current HOS case-mix methodology). CMS stated in the proposed rule that this "all-or-nothing" approach for each group of adjusters may not be as efficient as alternative approaches for handling missing case-mix adjusters. Under the proposed change, when an adjuster is missing for a beneficiary, it would be replaced with the mean value for that adjuster for other beneficiaries in the same contract who also supply data for the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures. This proposed approach has been used for the Medicare Advantage and Prescription Drug Plan CAHPS surveys for many years (see 2021 Medicare Part C & D Star Ratings Technical Notes Attachment A for a description of the CAHPS case-mix methodology). In simulation models, this approach either outperformed the current approach for predicting outcomes or matched the current approach. The proposed rule also explained how the proposed approach is easier to implement than the current approach as replacing the missing adjuster values with the contract mean scores for those adjusters rather than deleting the grouping of adjusters is less burdensome because it involves fewer steps and is easier to replicate and understand.

Second, we proposed to increase the minimum required denominator from 30 to 100 for the two measures. The proposed increase to the minimum denominator would bring these measures into alignment with the denominator requirements for the HEDIS measures that come from the HOS survey and increase the reliability for these measures compared to the current reporting threshold of 30.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: A majority of commenters expressed support for a simplified case-mix methodology, increased minimum denominator, and CMS's continued efforts to improve the quality and transparency of HOS measures. Some commenters stated that the new methodology for dealing with missing data will make the case-mix algorithm more accurate and help ensure fair and comparable contract level results by strengthening the measures' ability to adjust for beneficiary level differences. A commenter suggested removing HOS measures from the Star Ratings entirely, but most who expressed concerns about the proposed changes recommended CMS move the two HOS outcome measures to the display page for 2 years to allow stakeholders sufficient time to review. Some commenters noted that these changes are substantive.

Response: CMS appreciates the support for the proposed methodological changes. CMS agrees that the case-mix change is a substantive update as described at § 422.164(d)(2), so the provision there for placing an updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings applies. Thus, CMS will move these two HOS outcomes measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, as updated, to the display page for the 2024 and 2025 Star Ratings. Though CMS has the option of retaining the current specifications of these outcome measures in Star Ratings while stakeholders review and study the updated measures, our regulations do not require their retention during this interim period. Given the importance of patient-reported outcome measures in the Star Ratings program, CMS is opting to let stakeholders review the updated measures on the display page without simultaneously considering an alternate specification in the Star Ratings. We explained in the April 2018 final rule that we may continue use of a legacy measure if the updated measure expands the population covered in the measure or the measure otherwise is critical to the Star Ratings (83 FR 16537).

Comment: A commenter stated that these two HOS measures reflect experiences, not outcomes, and therefore should not be weighted as outcome measures. Another commenter stated that it is inappropriate to assign self-reported measures the weight of 3. A few commenters suggested CMS reduce the weight of the two HOS outcome measures to 1.5 or 2. Several commenters requested CMS clarify the weight of the two updated measures once they are reintroduced to the Star Ratings.

Response: The Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure both focus on key outcomes for a health plan: improving or maintaining the physical health and mental health of its enrollees. These measures reflect the outcomes of the plan's entire membership based on the members' perceptions of their own health. Thus, these measures do not measure patient experiences or beliefs about the health plan but measure changes over 2 years in the physical and mental health status of the enrollees in an MA contract. The weights of measures are assigned by measure type as codified at § 422.166(e). These measures (Improving or Maintaining Physical Health and Improving or Maintaining Mental Health) are considered outcome measures; thus, as codified at § 422.166(e)(1)(i), they receive a weight of 3. Under CMS's process to add, update, and remove measures used to calculate the Star Ratings codified at § 422.164, substantive updates to an existing measure result in the updated measure being on the display page for at least 2 years prior to its reintroduction to the Star Ratings. For weighting purposes, a substantively updated measure is treated as a new measure, and as described at § 422.166(e)(2), will receive a weight of 1 for the first year in the Star Ratings. In subsequent years, an updated measure is assigned the weight associated with its category. Thus, the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures will receive a weight of 1 in the 2026 Star Ratings and a weight of 3 in the 2027 Star Ratings and beyond.

Comment: Several commenters expressed concern about the cultural relevance of the survey questions, the applicability of the two HOS outcome measures to the LIS/DE and

disabled populations, and the robustness of the case-mix models to control for these differences. A commenter suggested the Improving or Maintaining Physical Health measure conflates functional status with health and pointed out that persons with functional limitations can still be in good health. Another commenter questioned the role of death in the statistical adjustment models that examine changes in expected physical health.

Response: There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best to control for their impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries within a contract or across contracts over time. CMS also continues to test and refine the HOS instrument with these issues in mind to ensure that survey questions are relevant to different populations. The current longitudinal measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, adjust for a wide variety of beneficiary demographic and socioeconomic characteristics to control for differences in these characteristics across contracts. MA organizations are held accountable for risk-adjusted changes in functioning, including mortality, because to ignore death as a physical health outcome would result in misleading results. We agree that people with functional limitations can be in good health and this is accounted for in the Improving or Maintaining Physical Health measure since it examines person-level changes from a baseline period to a follow-up period 2 years later. The HOS methodology takes into account the case mix of enrollees within each plan and controls for pre-existing baseline differences, including age, sociodemographic characteristics, functional status, and chronic medical conditions as reported in the HOS survey, to statistically adjust each plan's expected outcomes, including survival rate, based on national averages when calculating the results for Improving or Maintaining Physical Health. Mortality is not considered in the calculation of Improving or Maintaining Mental Health.

Comment: Several commenters expressed concern about the HOS survey, including whether increasing the minimum denominator to 100 would improve the stability of the specific measures. A few commenters urged CMS to consider an even larger increase. Another commenter recommended that CMS not implement the change until there is clear evidence it will enhance measure stability in the Star Ratings. Several commenters suggested involving stakeholders in future changes to the survey methodology, because of their implications for measures. Many commenters noted that these are significant changes to specifications, while additional changes may also be needed to improve the measures, such as to further increase reliability and stability of the measures.

Response: We have considered stakeholder feedback in the development of measures of clinical outcomes in the Part C and Part D Star Ratings program. The HOS was developed over the course of 2 decades under the guidance of several Technical Expert Panels (TEPs) of industry experts and its survey questions are derived from well-established patient reported outcome measures (PROs) that reflect clinical standards. Patients are the ultimate source of information on patient outcomes and CMS is committed to developing meaningful measures for quality measurement and improvement that enhance outcomes for beneficiaries. CMS continues to solicit stakeholder feedback on PROs, most recently through the 2020 draft Call Letter dated January 30, 2019 and the Star Ratings TEP on April 30, 2019. Additionally, CMS routinely seeks broad stakeholder input regarding measure enhancements, while maintaining scientific objectivity and independence throughout the process.

Our analyses do not show volatility of HOS measures in the Star Ratings, and in particular of the two outcome measures, which because of their weight in the Star Ratings calculation are of most concern to plans and sponsors. As an example, most plans maintained or gained stars on HOS measures between 2019 and 2020, and while there is some movement in the Star Ratings, the change is generally not acute. Only one plan dropped from 5 stars to 1 star for Improving or Maintaining Physical Health, while 68 percent of plans had no change or an

increase in stars for the measure, and 85 percent had no change or an increase in stars for Improving or Maintaining Mental Health. Analyses of movement in Star Ratings for these outcome measures do not raise concerns about stability, even over longer periods of time.

While CMS does not have concerns about the stability of the two outcome measures derived from HOS, we understand how much plans have at stake in their HOS-derived Star Ratings. Out of an abundance of caution and to be responsive to stakeholder concerns, we are taking a number of steps. One is to increase the denominator size to further increase reliability. In addition, and as CMS stated in the 2021 Rate Announcement, we are exploring alternative PROs as potential replacements for the existing HOS outcome measures in the future; we are particularly interested in less complex replacements that would facilitate MA plans directing their quality improvement efforts on a health focus relevant to their enrollee population.

Comment: A commenter suggested the HOS survey should not be fielded during the COVID-19 pandemic because of the burden the survey places on plan members and the impact of the pandemic on their health, and recommended that HOS baselines be considered unavailable through 2023.

Response: As stated in the March 31st COVID-19 IFC (CMS-1744-IFC), CMS delayed the HOS survey for 2020 until the late summer so as not to risk the health and safety of survey vendor staff during the initial stages of the pandemic. Since survey vendors have put in place procedures to safely administer the surveys, consistent with the HPMS memo released on July 20, 2020 titled "2020 Medicare Health Outcomes Survey (HOS) and HOS-Modified (HOS-M)," CMS fielded the HOS and HOS-M surveys in mid-August through mid-November of 2020. Longitudinal studies like the HOS are vital to understanding the immediate and long-term impacts of the COVID-19 pandemic on beneficiaries and health care. The survey is voluntary for plan members so they are empowered to decide whether to respond.

Comment: A commenter requested help identifying their members who complete the survey so that they can do a root-cause analysis of any issues reported or found. The commenter

mentioned a long lag time of approximately 3 years between baseline survey administration and when plans receive results and requested real-time data on patient outcomes.

Response: It is by design that CMS does not provide the identity of respondents until both baseline and follow-up surveying are complete in order to preserve the integrity of the sample and reliability of the results. Patient outcomes cannot be calculated using only baseline data, since the outcomes measured through this survey are the changes in physical and mental health status over time. It is important to protect the confidentiality of the survey respondents to limit the possibility of plans focusing solely on baseline survey respondents for quality improvement (in order to achieve higher scores) rather than a broad segment of the plan enrollment (which would improve the quality of care provided to the plan's overall population). HOS is a cohort study, and each year, the survey is administered to a new cohort, or group, from each contract both at the beginning and end of a 2-year period. The analysis of longitudinal data is complex, but CMS is actively striving to decrease the timeframe between completion of follow-up survey data collection and distribution of performance measurement data while maintaining the usefulness, reliability, and accuracy of the measures. In addition, CMS is working toward improved presentation of HOS performance measurement results that will include updates to the annual baseline and performance measurement reports and enhancements to the HPMS HOS module, beginning in CY 2021.

Comment: A few commenters requested as much detail be made public about the statistics for HOS as CMS publishes for CAHPS.

Response: While the timing and presentation of HOS and CAHPS results differ, both surveys provide comprehensive information and reports to each contract describing contract-specific findings and also publish information about the methodology and case-mix adjustments. As HOS is a longitudinal survey and CAHPS is an annual, cross-sectional survey, there are differences in methodology and statistics. CMS provides stakeholders and the public with similar levels of transparency and detail on both surveys. HOS case-mix variables are published in each

contract's Performance Measurement Report and coefficients are published on the HOS website and in Attachment A of the Star Ratings Technical Notes each year. Contract-specific baseline reports are currently distributed to plans in the spring of the year following baseline data collection. Performance Measurement reports are distributed in the summer of the year following follow-up data collection. Star Ratings data and aggregate score analysis reports are available in the HOS module in HPMS to allow easier data validation and score comparisons at the contract, state, region, and national levels for the core HOS physical and mental health outcome measures. Additional information about HOS and its methodology can be found at www.HOSonline.org. While there are differences, we believe that the extent and scope of HOS data provided to organizations is more than sufficient and comparable to the CAHPS data furnished to plans.

Comment: A commenter expressed some concern about the overlap of existing measures with the measure proposed in the 2021 Advanced Notice.

Response: In the 2021 Advance Notice, we stated that we planned to post the longitudinal Physical Functioning Activities of Daily Living (PFADL) change measure on the 2021 and 2022 display pages and that we may consider that PFADL measure for the Star Ratings in the future, pending rulemaking. Prior to potentially proposing this measure through future rulemaking, CMS would submit this measure through the Measures Under Consideration process to be reviewed by the Measure Applications Partnership which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, as required by Section 3014 of the Affordable Care Act. The 2021 Advance Notice also stated that given the complexities of the existing HOS measures, CMS is committed to exploring alternative PROs to replace the existing HOS outcome measures. We are particularly interested in replacements that would be simpler and more direct for plans to use and to focus their quality improvement efforts. If we propose to add the PFADL measure to the Star Ratings in future rulemaking, we will consider using it to replace existing measures.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized in this final rule, we are finalizing the proposed specification changes for the Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure but for measurement year 2022 instead of 2021. These measures would be moved to display for the 2024 and 2025 Star Ratings as the case-mix specification change is substantive as described at § 422.164(d)(2) and returned to the Star Ratings program for the 2026 Star Ratings.

b. Proposed Measure Additions

As discussed in the April 2018 final rule (83 FR 16440), new measures may be added to the Star Ratings through rulemaking and §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4) provide for reporting new measures on the display page for a minimum of 2 years before they are added to the Star Ratings program. In advance of adopting new measures through rulemaking, CMS also solicits feedback using the Advance Notice and Rate Announcement process. CMS is working with the National Committee for Quality Assurance (NCQA) to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. In the 2019 Call Letter, CMS discussed these two potential new Part C measures and finalized them in the 2020 Call Letter for the 2020 display page, which used 2018 measurement year data. In the February 2020 NPRM, CMS proposed to add the HEDIS Transitions of Care and the HEDIS Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions measures to the 2023 Star Ratings covering the contract year 2021 performance period. We stated that we would have these new Part C measures on the display page for 3 years, starting with the 2020 display page, prior to adding them to the Star Ratings program. In addition, we also discussed in the proposed rule how we would follow the pre-rulemaking process that is used in other CMS programs under section 1890A of the Social Security Act. Both of these proposed measures were submitted and reviewed through that process.

(1) Transitions of Care (Part C)

The HEDIS Transitions of Care (TRC) measure is the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year: 1) notification of inpatient admission and discharge; 2) receipt of discharge information; 3) patient engagement after inpatient discharge; and 4) medication reconciliation post-discharge. The TRC measure was first placed on the 2020 display page.

We explained in the proposed rule how NCQA, based on stakeholder input, was exploring a few non-substantive measure specification changes. The first change, for all measure indicators, is to broaden the forms of communications from one outpatient medical record to other forms of communication such as admission, discharge, and transfer record feeds, health information exchanges, and shared electronic medical records. The second is to change the notifications and receipts from 'on the day of admission or discharge or the following day' to 'on the day of admission or discharge or within the following two calendar days.' A third is to change one of the six criteria of the Receipt of Discharge Information indicator from 'instructions to the primary care providers or ongoing care provider for patient care' to 'instructions for patient care post-discharge.' We stated how these three changes are considered non-substantive since they include additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A), add alternative data sources as described at § 422.164(d)(1)(v), and do not change the population covered by the measure. Our proposal therefore was to adopt the TRC measure with or without the updates NCQA was considering at the time the proposed rule was issued. After publication of the NPRM, we also discussed this measure in the CY 2021 Advance Notice and Rate Announcement, reiterating how NCQA was considering these three non-substantive updates to the measure that we currently have on display. The comments CMS received to the CY 2021 Advance Notice and Rate Announcement were similar to those being addressed here. These include requests for clarifications and additional

time to implement the measure, as well as concerns about the coordination of information especially with out-of-network providers.

The intent of this measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events. The TRC measure excludes members in hospice and is based on the number of discharges, not members. Currently the TRC measure is on the display page and we proposed to add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period. On July 1, 2020, NCQA published the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans[30] which included the listed measure specification changes to be implemented for data collected in 2021 covering the 2020 measurement period. Therefore, all three non-substantive updates have been adopted by the measure steward.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Many commenters fully support the intent of this measure which is to improve continuity of care for MA members as they transition from inpatient to outpatient settings.

Response: CMS thanks commenters for the support of this measure. The TRC measure has been on the display page since 2020 covering the 2018 measurement period and we believe it provides important information about MA plan quality. Under this final rule, CMS will keep this measure, with the updates NCQA finalized following the publication of the proposed rule, which included these measure specification changes to be implemented for data collected in 2021 covering the 2020 measurement period. The TRC measure will remain on the 2023 display page (for the 2021 measurement year) in light of the timing of this final rule, and will move off the display page for the 2022 measurement period for use in calculating the 2024 Star Ratings.

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[30] http://store.ncqa.org/index.php/performance-measurement.html#vol2).

Comment: Several commenters recommended that the measure indicators should include all providers who can appropriately support a beneficiary during a care transition, including providers other than PCPs. A commenter suggested that pharmaceutical outreach activities be included in the 'patient engagement after discharge' category.

Response: The measure does allow for a variety of provider types and care providers to take action to meet the intent of the TRC indicators. However, the information that is used to meet the numerator of each indicator must be documented in the outpatient record that is accessible by the PCP or ongoing care provider. An ongoing care provider is defined as "the practitioner who assumes responsibility for the member's care." This definition is provided in the measure specifications and is intentionally broad because NCQA recognizes there are a variety of provider types who might be coordinating patient care. As proposed and adopted, the specifications for this measure do include a variety of providers that may be taking over the responsibility of managing the patient's care. The TRC measure is for the most part focused on getting information into any outpatient record that is accessible to the PCP or ongoing care provider. Pharmaceutical outreach activities would be included in the 'patient engagement after discharge' category if they are included in the patient's outpatient records. The Medication Reconciliation indicator is the only indicator where a provider type is specified for who can take action since it specifies that medications must be reconciled by a prescribing practitioner, clinical pharmacist, or registered nurse.

Comment: A commenter argued that not only a patient's PCP but their plan should be notified of an admission and a discharge. Another commenter suggested that notifications of inpatient admissions and discharges should prioritize alignment for dually eligible members (that is, both the patient's Medicare and Medicaid providers should be notified).

Response: CMS appreciates these comments and shared them with NCQA, the measure steward. Currently, the measure only focuses on notifications that go to the PCP or ongoing care provider. The measure is specified for Medicare plans, so plans will determine the provider that

meets the intent of the measure (which may include Medicaid providers treating dually eligible enrollees). Although the measure only focuses on notifications that go to the PCP or ongoing care provider, there is nothing in this measure that would prevent notifications also going to the health plan, subject to otherwise applicable laws on privacy and disclosure of health information. Further, we still believe it is important to implement this measure since transitions from the inpatient setting often result in poor care coordination, including communication gaps between inpatient providers and the PCP or ongoing care provider; unplanned medication changes; incomplete diagnostic work-ups; and inadequate patient, caregiver, and provider understanding of diagnoses, medication, and follow-up needs. This measure will put more emphasis on these issues for both providers and health plans.

Comment: Some commenters suggested that the original timeframe for notifications is too short, especially for out-of-network facilities.

Response: In the proposed rule and in the 2021 Rate Announcement, we stated how NCQA is considering a revision to the timeframe for the Notification of Inpatient Admission and Receipt of Discharge Information indicators for this measure to "the day of admission or discharge, or within the following two calendar days." This change clarifies expectations for documentation related to admissions or discharges that take place over the weekend. This change was approved by NCQA's Committee on Performance Measurement following the release of the proposed rule and is included in the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans released on July 1, 2020, to be implemented for data collected in 2021 covering the 2020 measurement period. Starting with the 2022 Display measure, the TRC measure will include the expanded timeframe for the receipt of discharge information.

Comment: Several commenters stated that the composite nature of the measure may not appropriately account for variation of performance on the different elements and may not allow

for understanding of the individual components. A number of commenters suggested that the four components of the composite measure be reported as separate Star Ratings measures.

Response: To minimize the number of new Star Rating measures to lessen complexity in the Star Ratings program, CMS is planning to average the four components into one composite measure for reporting in the Star Ratings program. Currently, the four components and the composite measure that combines the four components are reported on the display page. The four components of this composite measure will continue to be reported as separate measures on the display page so as to be available to plans for use in their quality improvement projects and to other stakeholders who want an additional breakdown of the data even though only the composite measure will be used in the Star Ratings. The composite measure will be displayed on Medicare Plan Finder as one measure focused on TRC to simplify the information publicly available on the website for consumers and so as not to overwhelm them with too many measures. This approach allows CMS to publicly report all included data, while directing audiences to the most helpful level of complexity for the reported results.

Comment: Some commenters suggested the current Medication Reconciliation Post-Discharge measure should remain as a separate Star Ratings measure since they believe it drives improved outcomes, while others recommended retiring the current Medication Reconciliation measure after implementation of the TRC measure. Ultimately, commenters requested to know what impact the introduction of the TRC measure will have on the current Medication Reconciliation measure. A commenter suggested that if the Medication Reconciliation measure is to be incorporated into the TRC measure, NCQA should continue to permit organizations to use the hybrid data collection method.

Response: As noted in the proposed rule and the 2021 Rate Announcement, NCQA was considering revisions to the TRC measure to the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from "the outpatient medical record as well as other information accessible to the primary care provider or ongoing

care provider". This change, which is included in the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans released on July 1, 2020, will be implemented for the 2020 measurement year and enables the specification to capture additional communication forms (for example, admissions, discharges, and transfers feeds, shared electronic medical records) that occur regularly in the field and meet the intent of the TRC measure. This change also ensures that scores for the Medication Reconciliation Post-Discharge component of the TRC measure and the scores for the standalone Medication Reconciliation Post-Discharge measure currently in the Star Ratings match exactly. As such, the additional stand-alone Medication Reconciliation Post-Discharge measure would no longer need to be separately reported by health plans. The hybrid option for reporting the Medication Reconciliation component of the TRC measure will remain for the foreseeable future.

Comment: Some commenters stated that the recent changes to the TRC measure described in the proposed rule are substantive and so the measure should remain on the display page.

Response: CMS believes that the updates to this measure are non-substantive since they add additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A), include alternative data sources as described at § 422.164(d)(1)(v), and do not change the population covered by the measure. As discussed in the April 2018 final rule, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change is not considered substantive because the sponsoring organization generally benefits from that change. In addition, the type of administrative change made here has no impact on the current clinical practices of the plan or its providers. However, CMS has decided to delay the implementation of this measure to the 2022 measurement year for the 2024 Star Ratings year given the timing of this final rule and in recognition of the challenges of implementing new measures during the COVID-19 pandemic.

This will provide an additional year for plans prior to implementation in the Star Ratings program.

Comment: A few commenters recommended that the TRC measure not be included in the Star Ratings until it is further improved. Other commenters noted that processes are not always in place to provide notifications to PCPs in a consistent or timely manner, especially for out-of-network facilities. A commenter suggested that this measure is primarily a measure of data interoperability and exchange capabilities between providers, capabilities which are not under plans' control. Several commenters mentioned the substantial amount of medical review work entailed for this measure, especially for the notification of admissions and discharges. Plans often require physicians to submit records for abstraction which places a considerable burden on physician practices. In other words, although this measure is a plan measure, commenters pointed out that data collection is often the responsibility of physician groups and plans do not have sufficient control or involvement to achieve consistent high performance. Further, a commenter expressed concern that the measure moves away from NCQA's focus on moving towards more digital measures. Several commenters requested further clarity on measure specifications such as how plans should indicate the use of other acceptable communication forms for this measure.

Response: The intent of the TRC measure is to ensure a seamless transition from inpatient to outpatient settings for MA enrollees to improve the delivery and coordination of care following an inpatient stay. When a beneficiary moves from an inpatient to outpatient setting, there is often poor coordination of care, communication lapses between the inpatient and outpatient providers, inadvertent medication changes, and a lack of understanding among patients, caregivers, and providers about the follow-up and ongoing care needs following the hospitalization. Given the critical importance of a seamless transition from the inpatient to outpatient setting, CMS believes it is important to adopt the current measure and for plans to

make sure their providers are ensuring that there is a seamless transition between the inpatient to outpatient setting.

This measure is intended to address the very gaps in communication and interoperability that are noted in the comments. Unfortunately, the current state of standards and coding do not support a fully administrative or digital specification at this time. NCQA is continuing to work with standards developers on addressing this issue and will assess the feasibility of converting this measure to a fully administrative specification when the standards for information sharing and coding are updated to support such an approach. The measure assesses if the notification of admission or receipt of discharge information was received and documented within the timeframe specified in the measure and is agnostic about the form of communication for the Notification of Admission and Receipt of Discharge Information indicators. CMS shared these comments with NCQA, the measure steward, for consideration as they make future updates to this measure.

Comment: Some commenters stated this measure focuses on documentation of events rather than the substance of the transition experience.

Response: CMS believes this measure does focus on the substance and purpose of the transition experience, which is to improve health outcomes. The measure is not simply about documentation but about whether notification was made, discharge information was received, patients were engaged, and medication was reconciled. Poor hospital transitions are not only associated with poor health outcomes but also increased health care utilization and cost, duplicative medical services, medication errors, and increased emergency department visits and readmissions. Incentivizing better transition experiences, where these activities take place and are documented for a treating provider who furnishes post-discharge care, is an important goal served by this measure.

Comment: A commenter suggested that I-SNP members should be excluded from the measure.

Response: I-SNP members should be receiving the same care coordination as enrollees of other plan types so CMS believes it is appropriate to use this measure for such plans as well. NCQA has examined an exclusion for I-SNP members in the past and discussed this exclusion with its advisory panels. The panels agreed that I-SNP members should be included in the measure because this is a vulnerable population that requires care coordination. We agree with that conclusion and will use this measure for I-SNPs as well as other MA plans.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the addition of the Transitions of Care (Part C) measure in the Star Ratings program with a delay of 1 year in light of the timing of this final rule. That is, CMS will implement this measure using data from the 2022 measurement year for the 2024 Star Ratings year. This measure is currently on the display page with the current specifications. The Transitions of Care measure with the updates recently finalized by NCQA for the 2020 measurement year will be on the display page for 2022 and 2023 before being used in the 2024 Star Ratings. By delaying the addition of this measure to the Star Ratings program until 2024 Star Ratings, this also allows plans more time in recognition of the challenges of implementing new measures in the program during the COVID-19 pandemic.

(2) Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (Part C)

CMS proposed to add a new HEDIS measure assessing follow-up care provided after an emergency department (ED) visit for people with multiple high-risk chronic conditions. This measure is the percentage of ED visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. Eligible members whose ED visits are used in the measure must have two or more of the following chronic conditions: chronic obstructive pulmonary disease (COPD) and asthma;

Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack. The following meet the criteria to qualify as a follow-up service for purposes of the measure: an outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management. Patients with multiple chronic conditions are more likely to have complex care needs, and follow-up after an acute event, like an ED visit, can help prevent the development of more severe complications. We proposed to add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Many commenters fully support the intent of this measure which is to provide continuity and coordination of care to persons with multiple chronic conditions.

Response: CMS thanks commenters for the support of this measure.

Comment: Several commenters did not support the measure. Some suggested that the 7-day time period for receipt of a follow-up service is too short. Commenters argued that it can take more than 7 days for an ED claim to be processed and submitted to a plan, actions which must occur before a PCP is aware of a patient's ED visit. They stated this situation is compounded by the fact that ED visits require no preauthorization, so a PCP has no forewarning of a potential ED visit. They stated that though there are many actions which define a follow-up service - such as outpatient or telehealth physical or behavioral health visits, phone visits, or care management services - the average time to schedule a follow-up meeting with a PCP is typically longer than 7 days.

Response: CMS continues to believe that the measure is appropriate for use in the Star Ratings. This measure is focused on a very vulnerable population that should have prompt follow-up after a visit to the ED. The 7-day timeframe was recommended by NCQA's advisory

panels and chosen for its potential to improve quality of care, especially because patients with multiple chronic conditions who do not receive follow-up after visiting the ED show increased rates of hospital admissions and 30-day readmissions. In addition, the lack of real-time data exchange is a critical system issue that the NCQA advisory panels cited should be addressed by this measure.

The Medicare population includes a large number of individuals and older adults with high-risk multiple chronic conditions who often receive care from multiple providers and settings and, as a result, are more likely to experience fragmented care and adverse healthcare outcomes, including an increased likelihood of ED visits.[31,32] Medicare beneficiaries with multiple chronic conditions require high levels of care coordination, particularly as they transition from the ED to the community. During these transitions, they often face communication lapses between ED and outpatient providers and inadequate patient, caregiver and provider understanding of diagnoses, medication and follow-up needs.[33,34,35,36] This poor care coordination results in an increased risk for medication errors, repeat ED visits, hospitalizations, nursing home admissions, and death.[37,38] Medicare beneficiaries with multiple chronic conditions not only experience poorer health outcomes, but also greater health care utilization (for example, physician use, hospitalizations,

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[31] AHRQ. 2010. Multiple Chronic Conditions Chartbook. "2010 Medical Expenditure Panel Survey Data." https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf (Accessed January 11, 2017)

[32] Agency for Healthcare Quality and Research (AHRQ). 2012. "Coordinating Care for Adults with Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions." https://pcmh.ahrq.gov/sites/default/files/attachments/coordinating-care-for-adults-with-complex-care-needs-white-paper.pdf

[33] Altman, R., J.S. Shapiro, T. Moore and G.J. Kuperman. 2012. "Notifications of hospital events to outpatient clinicians using health information exchange: a post-implementation survey." *Journal of Innovation in Health Informatics* 20(4).

[34] Coleman, E.A., R.A. Berenson. 2004. "Lost in transition: challenges and opportunities for improving the quality of transitional care." *Annals of Internal Medicine* 141(7).

[35] Dunnion, M.E., and B. Kelly. 2005. "From the emergency department to home." *Journal of Clinical Nursing* 14(6), 776–85.

[36] Rowland, K., A.K. Maitra, D.A. Richardson, K. Hudson and K.W. Woodhouse. 1990. "The discharge of elderly patients from an accident and emergency department: functional changes and risk of readmission." *Age Ageing* 19(6), 415–18.

[37] Hastings, S.N., E.Z. Oddone, G. Fillenbaum, R.J. Sloane and K.E. Schmader. 2008. "Frequency and predictors of adverse health outcomes in older Medicare beneficiaries discharged from the emergency department." *Medical Care* 46(8), 771–7.

[38] Niedzwiecki, M., K. Baicker, M. Wilson, D.M. Cutler and Z. Obermeyer. 2016. "Short-term outcomes for Medicare beneficiaries after low-acuity visits to emergency departments and clinics." *Medical Care* 54(5), 498–503.

ED use, and medication use) and costs (for example, medication, out-of-pocket, and total health care).[39] Medicare beneficiaries with multiple chronic conditions are some of the heaviest users of high-cost, preventable services such as those offered by the ED.[40,41] An estimated 75 percent of health care spending is on people with multiple chronic conditions.[42,43] Improving the timeliness of communications about ED care, as required to perform well on these measures, should not only improve care, but reduce costs as well. Because of this context, we believe that collection and use of this measure in the Star Ratings is important in order to incent contracts to provide the best care possible for vulnerable enrollees.

Comment: Some commenters noted that the measure judges plans for actions that facilities must take. Plans stated they are not always informed by facility providers of ED visits, especially by out-of-network or out-of-area facilities. Plans claimed sending notifications of an ED visit is under the sole influence of the facility. On the other hand, facility providers argued the measure puts burden on them to provide information to the plans on a very quick basis. Both plans and facility providers stated that data sharing between plans and facilities is difficult. A commenter suggested this measure might be more suited as a facility quality measure.

Response: CMS recognizes the challenges inherent in quickly and successfully communicating patient information among different types of providers. CMS believes, however, that plans are in a critical position to help coordinate the care of their members and help improve the timeliness and quality of the communications that occur among EDs, inpatient facilities, and outpatient providers. This is important because the Medicare population includes a large number

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[39] Lehnert, T., D. Heider, H. Leicht, S. Heinrich, S. Corrieri, M. Luppa, S. Riedel-Heller and H.H. Konig. 2011. "Review: health care utilization and costs of elderly persons with multiple chronic conditions." *Medical Care Research & Review* 68(4), 387–420.
[40] CMS. 2012. *Chronic Conditions among Medicare Beneficiaries, Chartbook,* 2012 Edition. Baltimore, MD. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf (Accessed July 19, 2016)
[41] Lochner, K.A., and C.S. Cox. 2013. *Prevalence of multiple chronic conditions among Medicare beneficiaries, United States, 2010.* https://www.cdc.gov/pcd/issues/2013/12_0137.htm (Accessed January 11, 2017)
[42] CDC. 2009. *The power of prevention: Chronic disease…the public health challenge of the 21st century.* http://www.cdc.gov/chronicdisease/pdf/2009-power-of-prevention.pdf (Accessed January 24, 2017)
[43] Care Innovations. 2013. "Cost Control for Chronic Conditions: An Imperative for MA Plans." The Business Case for Remote Care Management (RCM). https://www.rmhpcommunity.org/sites/default/files/resource/The%20Business%20Case%20for%20RCM.pdf (Accessed January 24, 2017)

of individuals and older adults with high-risk multiple chronic conditions (MCC) who often receive care from multiple providers and settings and, as a result, are more likely to experience fragmented care and adverse healthcare outcomes, including an increased likelihood of ED visits. NCQA's first year analysis results for this measure indicated that most MA contracts (approximately 92 percent) were able to report a valid rate for the measure the first year that the measure was implemented.

Comment: Some commenters wanted CMS to delay the inclusion of the measure in the Star Ratings program and suggested that it will take time to establish data sharing protocols among providers and facilities, especially with out-of-network facilities. They stated data sharing protocols are challenging.

Response: The Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions measure was placed on the 2020 display page covering the 2018 measurement year. This measure was slated to remain on the display page through 2022. This measure, however, will remain an additional year on the display page since CMS is now delaying the implementation of this measure to the 2022 measurement or performance year and the 2024 Star Ratings year given the timing of this final rule. This gives plans more time to establish data sharing protocols that allow them to facilitate timely follow-up after ED visits.

Comment: Some commenters requested modifications of the measure specifications. For example, some commenters wanted the list of services categorized as follow-up services expanded to include community resources, medication reconciliation, and services from long-term care facilities. Also, commenters suggested excluding patients released from the ED to skilled nursing facilities; not including managed long-term services and supports plans since they already have follow-up services in place; excluding inappropriate ED visits; excluding observations stays as a follow-up service; and including metabolic acidosis, cancer, and diabetes as chronic conditions.

Response: The purpose of this measure is to focus on the care provided by MA plans. CMS is working to expand efforts to better evaluate health plans' successes at effective care coordination, and we believe the addition of this measure will both add to our understanding of plan efforts to effectively coordinate care as well as encourage all plans to further focus on improving care coordination for their vulnerable enrollees. We have shared these comments with NCQA, the measure developer, and they will consider additional exclusions and inclusions for future updates to the measure, but we believe the measure as currently specified gets at the direct efforts of MA plans coordinating the care of Medicare enrollees with multiple high-risk chronic conditions following an ED visit. Therefore, we are adopting the measure for use in the Star Ratings program.

Comment: A few commenters mentioned that since psychiatric diagnoses are always coded secondary to any physical diagnosis, there are HIPAA and confidentiality concerns about disclosing information on patients with secondary substance abuse or psychiatric diagnoses. Such disclosures require patient consent. In addition, some commenters stated that it can be difficult to accurately capture data to track appropriate follow-up psychiatric care given confidentiality concerns.

Response: MA plans and providers must comply with applicable privacy and information protection laws and CMS is not providing guidance in this final rule on the specific assertions about restrictions under applicable privacy and information protection laws, such as HIPAA or 45 CFR part 2. However, the measure does not require a plan or facility to violate applicable law. CMS and NCQA will continue to monitor any issues that might arise due to patient confidentiality or consent with regard to information sharing. NCQA, in its testing protocols, has not observed this issue to cause any major barriers to reporting this measure to date.

Comment: A couple of commenters recommended risk adjustment to account for plans with large low socio-economic status, dual eligible and homeless populations.

Response: We will include this measure as one of the candidate measures for the calculation of the Categorical Adjustment Index (CAI). As stated at §§ 422.166(f)(2)(iii) and 423.186(f)(2)(iii), CAI values are determined using all measures in the candidate measure set after applying the following exclusions: the measure is already adjusted for socio-economic status, the measure focuses on a plan or provider-level issue, the measure is scheduled for retirement in the Star Ratings year that the CAI is being applied, or the measure is a SNP-only measure. It is also important to note that this measure focuses on prompt follow-up for beneficiaries with multiple chronic conditions which is a very vulnerable population. If additional risk factors such as low socio-economic status further increase these patients' levels of vulnerability, it is even more critical for this population to have prompt follow-up after visiting the ED. Further, this measure takes into account a wide variety of follow-up services to count, including telephone calls and telehealth visits, making it easier for the plan to tailor the follow-up to the enrollee or to specific enrollee populations. For example, if a beneficiary does not have transportation to get to an appointment with a provider, the follow-up can happen through a phone call with the provider.

Comment: A couple of comments stated that no new measures should be introduced into the Star Ratings program this year given the COVID-19 pandemic.

Response: Under our proposal this measure was slated to remain on the display page through 2022 Star Ratings and be used for the 2023 Star Ratings. This measure, however, will remain on the display page through 2023 since CMS is now delaying the implementation of this measure to the 2022 measurement year and the 2024 Star Ratings as a result of the timing of this final rule. Additionally, this will give plans an additional year to adjust to this new measure given any challenges from the COVID-19 pandemic.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the

addition of the Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (Part C) measure in the Star Ratings program beginning with the 2022 measurement year and the 2024 Star Ratings. This delay compared to our proposal addresses both the timing of this final rule and the recognition that it is more challenging to adapt to new measures during the COVID-19 pandemic.

The changes to the Star Ratings measures we are adopting in this final rule are summarized in Table D1.

TABLE D1: NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2022

The measure descriptions listed in this table are high-level descriptions. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes*, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually, consistent with the applicable final rules adopting changes to the Star Ratings system. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2020 are produced in the fall of 2019. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2020, the measurement period is referencing the 1/1/2018-12/31/2018 period.

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
Part C Measure								
Transitions of Care (TRC)	Percentage of discharges for members 18 years of age and older who had each of the following: 1) notification of admission and post-discharge: 2) receipt of discharge information, 3) patient engagement, and 4) medication reconciliation.	Managing Chronic(Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Available	Clustering	MA-PD and MA-only
Follow-up after ED Visit for People with Multiple High-Risk Chronic Conditions (FMC)	Percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Available	Clustering	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
	chronic conditions: COPD and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.							

*NCQA HEDIS Measurement Year 2020 & Measurement Year 2021, Volume 2

5. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

We proposed to modify §§ 422.166(i)(8) and 423.186(i)(6) to clarify the rules for how the adjustment for extreme and uncontrollable circumstances would apply where there are missing data, including data missing because of a data integrity issue as defined at §§ 422.164(g)(1) and 423.184(g)(1). In addition, we solicited comment in the proposed rule on a previously adopted policy regarding application of the adjustment for extreme and uncontrollable circumstances where a contract's service area was affected by disaster(s) in successive years, including whether additional changes were necessary.

We explained in the February 2020 proposed rule how we adopted the current policy for treating contracts impacted by separate disasters that occur in successive years taking into account concerns about looking back too many years for contracts affected by disasters multiple years in a row; we are also concerned about including too many measurement periods in 1 year of Star Ratings. We explained that the adjustment for extreme and uncontrollable circumstances also must consider operational feasibility, because using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings. We reiterated that we must balance concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters. We explained as well how we believe that the current regulation achieves an appropriate balance.

We finalized in the April 2019 final rule a policy effective for the 2022 Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by different disasters for 2 consecutive years. Such multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract

reverts to their 2021 Star Rating on a given measure for the 2022 Star Ratings, the 2021 Star Rating is not used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the contract's 2022 Star Rating would have been, absent any disaster adjustments.

The rule for treatment of multiple year-affected contracts was established to limit the age of data that will be carried forward into the Star Ratings. We use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We finalized this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. The provisions at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) include this rule for how ratings for these measures are adjusted in these circumstances. We solicited comment on this policy and whether further adjustments are necessary.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: A commenter appreciated CMS's proposed amendment to add to §§ 422.166(i)(8) and 423.186(i)(6) to clarify that missing data include situations where there is a data integrity issue as defined at §§ 422.164(g)(1) and 423.184(g)(1).

Response: We appreciate the support for the data integrity policy. Sections 422.166(i)(8) and 423.186(i)(6) currently provide that for an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described elsewhere in the regulation applies. We proposed a clarification and are finalizing changes to state that the term "missing data" under the rule includes data where there is a data integrity issue as defined in §§ 422.164(g)(1) and 423.184(g)(1). Under the rules as finalized, when there is a data integrity issue in the current or previous year, the final measure rating comes from the current year.

Comment: A few commenters supported CMS's policy to adjust Star Ratings for FEMA-designated Individual Assistance area disasters for contracts that have been affected by consecutive year disasters and had at least 25 percent of enrollees residing in those areas. A commenter suggested CMS consider lowering this percentage if the situation warrants, and another requested that CMS drop the threshold for relief below the current 25 percent to determine the contracts impacted and the current 60 percent to exclude contracts from the cut point calculations for doubly-affected contracts or provide relief based on the proportion of members likely impacted.

Response: We appreciate the support for the methodology for multiple year-affected contracts codified at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv). We continue to believe that the 25 percent threshold is appropriate in the vast majority of situations where the adjustment for extreme and uncontrollable circumstances would apply. The 25 percent threshold for measure star adjustments was codified in the April 2019 final rule to ensure that disaster adjustments are limited to contracts that we believe may have experienced a real impact from extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. We believe using the same 25 percent threshold for multiple year-affected disaster adjustments as for single year disaster adjustments is appropriate for the same reasons and to ensure administrative efficiency and transparency for applying this adjustment. We addressed similar concerns about the 25 percent threshold being too high in the April 2019 final rule (84 FR 15773 through 15774). The 60 percent threshold for excluding numeric values for affected contracts from cut points and Reward Factor calculations was also codified in the April 2019 final rule; that threshold is not relevant to the adjustment for multiple year-affected contracts and we do not believe that it is necessary or appropriate to change that threshold here. We explained that threshold in the April 2019 final rule (84 FR 15771 through 15774).

Comment: A few commenters requested that CMS reconsider the current policy for adjusting Star Ratings calculations in consecutive years of extreme and uncontrollable

circumstances and instead consider a multi-year lookback period, which would include the most recent period not impacted by extreme and uncontrollable circumstances. A commenter suggested CMS could use the parent organization average or the industry average instead.

Response: As we stated in the April 2019 final rule, we are concerned about looking back too many years for contracts affected by disasters multiple years in a row, as well as about including too many measurement periods in 1 year of Star Ratings. This could result in looking back different years for different contracts since we would need to look back to the latest year with no disasters for each contract. Carrying forward very old data into the Star Ratings for many years, especially in situations where large numbers of contracts are impacted by disasters in a given year or in areas that are more prone to disasters, could erode incentives for plans to provide high quality care for their beneficiaries even in the face of a disaster.

Further, using a multi-year lookback for contracts affected by disasters would be operationally very complex since for each contract we could be comparing to a different year of data that is unaffected, in particular in areas that are prone to disasters, and could put CMS at risk of not producing Star Ratings in time for open enrollment. It would also make it difficult to provide transparency to plans and could be misleading to consumers. CMS has an obligation to ensure that Star Ratings data are useful for providing comparative plan information to beneficiaries because part of the purpose and authority for the Star Ratings is to provide comparative information to beneficiaries under sections 1851(d) and 1869D-1(c) of the Act. We strive to provide as up-to-date and accurate information on plan quality and performance as possible to beneficiaries. For areas that are prone to disasters in particular, beneficiaries deserve to have some indication if that means that the plan they are considering does not perform well when a disaster strikes or maintains high quality ratings despite those challenges. We finalized the existing policy for contracts that are affected by disasters in successive years in order to balance concerns about either using older data or using data based on performance impacted by consecutive disasters.

As to the suggestion to assign the parent organization average or industry average for contracts that have been impacted by disasters for multiple years, we do not believe this appropriately holds contracts accountable for their performance or allows them to distinguish themselves in disaster situations. We remind contracts that §§ 422.504(o) and 423.505(p) require MA organizations and Part D sponsors to develop, maintain, and implement a business continuity plan that ensures restoration of operations following disruptions such as disasters. Contracts are still responsible for providing care to their beneficiaries during disasters, so it would not be fair or appropriate to simply award them a rating that is based on the performance of other plans. Further, the Star Ratings are used for payment purposes and using the performance of other plans as the basis to award a quality bonus increase or increased rebate percentage to a contract is inconsistent with the purpose of those payment policies to reward MA organizations that excel.

Comment: A commenter suggested CMS could consider a hold harmless provision for plans with significant losses in Star Ratings across the multi-year lookback period.

Response: The disaster policies already address how extreme and uncontrollable circumstances may have a negative impact on the Star Ratings of an MA or Part D plan. We do not believe additional hold harmless provisions are needed for multiple year-affected contracts as it could weaken plan accountability and incentives to provide high quality care in disaster situations.

Comment: Several commenters suggested CMS expand the current rule for contracts impacted by two different disasters in consecutive years to include contracts impacted by a single disaster spanning multiple years.

Response: The introductory language of paragraph (i) of both §§ 422.166 and 423.186 states that we use the incident start date to determine which year of Star Ratings can be adjusted for a particular disaster, regardless of whether the incident period lasts until another calendar year. As we explained in the April 2019 final rule (84 FR 15774), in some cases the incident

period end date changes, which would make it difficult operationally to determine which Star Ratings year is impacted. We believe limiting adjustments for a single disaster to 1 year is appropriate to avoid adversely impacting CMS's operational timelines for analyzing data and calculating Star Ratings. For example, if a disaster is extended into the next measurement year we would potentially need to recalculate and reissue ratings. We also want to limit the impact and effects on contracts that do meet the definition of "affected contract." We are concerned, for example, about the integrity of the ratings and reliability of the comparisons if cut points do not take into account the performance of an increasing number of affected contracts or if cut points have to be recalculated after they are released. We also want to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years.

Comment: A couple commenters requested clarification about how CMS handles situations where a contract is affected by multiple disasters in the same year.

Response: We use the percent of enrollment impacted by qualifying disasters to determine eligibility for disaster adjustments. That is, contracts impacted by multiple qualifying disasters in the same year are eligible for the disaster relief as long as a total of 25 percent or more of their enrollees reside in Individual Assistance areas. CMS rolls up the enrollment for each contract at the state/county level; when more than one enrollment period applies (that is, because the contract was affected by more than one disaster), an average of the enrollments from each of corresponding enrollment periods where the contract was affected is used to calculate the total percent of a contract's enrollees in a FEMA-designated Individual Assistance area during extreme and uncontrollable circumstances. This is described in detail in the Medicare Part C & D Star Ratings Technical Notes Attachment Q: Identification of Contracts Affected by Disasters (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData, page 143 of 2020 Star Ratings Technical Notes).

Comment: We received a number of comments about the impact of COVID-19 on Star Ratings, for example asking whether and how CMS would adjust for the impact of COVID-19 for 2021 Star Ratings and beyond.

Response: The public health emergency incident start date for COVID-19 was in 2020, so adjustments under the extreme and uncontrollable events policy at §§ 422.166(i) and 423.186(i) will apply to the 2022 Star Ratings. The March 31st COVID-19 IFC addressed the immediate impact of the pandemic on the Part C and D Star Ratings program and made additional modifications for the 2022 Star Ratings, in recognition that the COVID-19 pandemic may impact performance on the Star Ratings measures during the 2020 measurement period. CMS will continue to monitor the impact of COVID-19 on the healthcare system and Part C and D plans. The September 2nd COVID-19 IFC modifies the calculation of the 2022 Part C and D Star Ratings to address the application of the extreme and uncontrollable circumstances policy. We direct readers to our summary of those two interim final rules with comment in section IV.D.1 of this final rule.

Comment: Several commenters requested that CMS expand the current extreme and uncontrollable circumstance policy for single year disasters, for example to include HHS-declared public health emergencies, Fire Management Assistance Grant (FMAG) declarations, governor declarations of a state of emergency, or state-level public health emergencies that extend beyond a national emergency period. A few stated if a contract gets the same Star Rating in both years, CMS should take the higher of the 2 years' measure scores in order to ensure that plans and beneficiaries are truly held harmless in the event of a disaster. Several commenters suggested modifications to how the improvement measures are handled when there are disasters. For example, we received suggestions to hold contracts harmless in improvement when there are disasters.

Response: The changes suggested by commenters for expanding the adjustments for single year disasters are significant in scope and of the type that would require analysis and

consideration by CMS before proposing changes to the current regulations. As we noted in the April 2019 final rule (84 FR 15773), we use the Star Rating for the measure-level comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. We use the corresponding measure scores for improvement calculations in order to maintain consistency in the years being compared. We only revert to the previous year's measure Star Rating if it is higher (§§ 422.166(i)(2)(iv), 422.166(i)(3)(iv), 422.166(i)(4)(v), 422.166(i)(6)(i), 423.186(i)(2)(iv), and 423.186(i)(4)(i)).

Summary of Regulatory Changes

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the addition of §§ 422.166(i)(8) and 423.186(i)(6) as proposed. These changes are applicable to the 2022 measurement year and the 2024 Star Ratings. We do not believe additional revisions to the rules for multiple year-affected contracts described at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) are necessary to address the impacts of the PHE for the COVID-19 pandemic in light of the September 2nd COVID-19 IFC.

6. Quality Bonus Payment Rules (§§ 422.162(b)(4) and 422.166(d)(2)(vi))

We proposed several amendments to §§ 422.162(b)(4) and 422.166(d)(2)(vi) to codify our current policies for using the Star Ratings to calculate quality bonus payment percentage increases (QBPs) and determine beneficiary rebates for MA organizations.

The Affordable Care Act amended sections 1853(n) and 1853(o) of the Act to require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star Quality Rating system. The Affordable Care Act also amended section 1854(b)(1)(C) of the Act to change the share of savings available to MA organizations and that they must provide to enrollees as the beneficiary rebate, mandating that the level of rebate is tied to the level of an MA organization's QBP rating. As a result, beginning in 2012, quality as measured by the 5-star Quality Rating System directly affected the monthly payment amount MA organizations receive from CMS. At

the time the QBPs were implemented, CMS codified at § 422.260 an administrative review process available to MA organizations for payment determinations based on the quality bonuses. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal request under § 422.260(c) if they believe there is a calculation error or incorrect data are used.

In the April 2018 final rule, we codified at § 422.160(b)(2) that the ratings calculated and assigned under this subpart are used to provide quality ratings on a 5-star rating system used in determining QBPs and rebate retention allowances. Historically, the QBP rating rules have been announced through the Advance Notice and Rate Announcement since section 1853(b) of the Act authorizes an advance notice and rate announcement to solicit comment for proposed changes and announce changes to the MA payment methodology. The QBPs are used as part of setting the MA benchmarks and capitation rates for counties (and thus, MA service areas) each year. As we have codified in regulation the methodology for the Star Ratings over the last couple of years, we proposed in the February 2020 proposed rule to clarify the rules around assigning QBP ratings, codify the rules around assigning QBP ratings for new contracts under existing parent organizations, and amend the definition of new MA plan that is codified at § 422.252 by clarifying how we apply the definition. Our proposal was to codify current policy (for how we have historically assigned QBP ratings) as generally adopted and implemented through the section 1853(b) process, without substantive changes.

Historically, for contracts that receive a numeric Star Rating, the final QBP rating released in April for the following contract year would be the contract's highest rating as defined at § 422.162(a) (that is, overall or summary rating). Section 422.260(a) states that the QBP determinations are made based on the overall rating for MA-PDs and the Part C summary rating for MA-only contracts. We proposed to add language at § 422.162(b)(4) stating that for contracts that receive a numeric Star Rating, the final QBP rating is released in April of each year for the following contract year and that the QBP rating is the contract's highest rating, as

that term is defined at § 422.162(a). We also proposed to clarify in the regulation text that the QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies. For example, the 2020 QBPs were released in April 2019 and based on the Star Ratings published in October 2018. For MA contracts that offer Part D, the QBP rating would be the numeric overall Star Rating. For MA contracts that do not offer Part D (MA-only, MSA, and some PFFS contracts), the QBP rating would be the numeric Part C summary rating. We also proposed adding language at § 422.162(b)(4)(ii) clarifying that the contract QBP rating is applied to each plan benefit package under the contract.

We explained in the February 2020 proposed rule that if a contract does not have sufficient data to calculate and assign Star Ratings for a given year because it is a new MA plan or low enrollment contract, § 422.166(d)(2)(v) provides the rules for assigning a QBP rating. That regulation references the definitions at § 422.252. We proposed to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. We address that proposal in section IV.D.2 of this rule.

We also proposed to add rules at § 422.166(d)(2)(vi) for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of either low enrollment contracts or new MA plans at § 422.252. Our proposal was to codify the policy that has been in place since the 2012 Rate Announcement: any new contract under an existing parent organization that has had MA contract(s) with CMS in the previous 3 years receives an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. We also addressed that policy in a proposed rule for CY 2012 that appeared in the Federal Register on November 22, 2010 ("Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes") (75 FR 71190, 71219) and the related final rule that appeared in the Federal Register on April 15, 2011 (76 FR 21432, 21486 through 21490). We

explained in the February 2020 proposed rule that we intended for this policy to continue uninterrupted so that the calculation of QBPs remains stable and transparent to stakeholders. Codifying the policy explicitly, as well as how it is applied, would serve this purpose.

We proposed to add at § 422.166(d)(2)(vi)(A) that any new contract under an existing parent organization that has other MA contracts with numeric Star Ratings in November (when the preliminary QBP ratings are calculated for the contract year that begins 14 months later) would be assigned the enrollment-weighted average of the highest Star Rating of all other MA contracts under the parent organization that will be active as of April the following year. The Star Ratings used in this calculation would be the whole or half Star Ratings that are publicly displayed. For the 2021 QBPs, for any new contracts under an existing parent organization, we explained how the policy would be applied as follows:

(i) We identify the parent organization of the new contract in November 2019.

(ii) We identify the MA contracts held by that parent organization in November 2019, when the preliminary 2021 QBP ratings are posted for review. For preliminary QBP ratings, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2019 that we anticipated to still be in existence and held by that parent organization in April 2020.

(iii) Using the enrollment in those other MA contracts as of November 2019, we calculated the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iv) In April 2020, we update the enrollment-weighted average rating based on any changes to the parent organization of existing contracts, using the November 2019 enrollment in the contracts. The enrollment-weighted average rating includes the ratings of any contract(s) that the parent organization has acquired since November 2019. This enrollment-weighted average is used as the 2021 QBP rating for the new MA contract under the parent organization for payment in 2021. We release these QBP ratings in April of the year before the payment year (for 2021 QBPs, in April of 2020).

Because our proposal was to codify existing and current policy without change, we followed these steps to identify the QBP ratings for new contracts of existing MA parent organizations for 2021 QBPs.

We proposed to add at § 422.166(d)(2)(vi)(B) that if a new contract is under a parent organization that does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years. The QBP rating would be the enrollment-weighted average of the MA contracts' highest-level Star Ratings from the most recent year that had been rated for that parent organization. We explained using an example: if in November 2019 there were no other MA contracts under the parent organization with numeric 2020 Star Ratings, we would go back first to the 2019 Star Ratings and then the 2018 Star Ratings. Under our existing policy, and thus under the proposal, if there were MA contract(s) in the parent organization with Star Ratings in any of the previous 3 years, the QBP rating was the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year rated. Under our existing policy, and thus under the proposal, the Star Ratings used in this calculation would be the rounded Star Ratings (whole or half star) that are publicly displayed on www.medicare.gov.

We explained in the February 2020 proposed rule how the policy works by using another illustration for the 2021 QBPs. For a new contract(s) under a parent organization that did not have any MA contracts in November 2019:

(i) We identify the MA contracts held by that parent organization in November 2018. If the parent organization had other MA contracts in November 2018, we use the numeric Star Ratings issued in October 2018 for those MA contracts that were held by the parent organization in November 2018.

(ii) Using the enrollment in those other MA contracts as of November 2018, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This enrollment-weighted average is used as the 2021 QBP rating for the new MA contract for that parent organization, for payment in 2021 and is released to the MA organization for the new contract in April of 2020.

Because our proposal was to codify existing and current policy without change, we followed these steps for the 2021 QBPs where applicable. And for any new contract(s) under a parent organization that did not have any MA contracts in November 2018 and 2019, we provided an illustration (again for the 2021 QBPs) as follows:

(i) We identified the MA contracts held by that parent organization in November 2017. If the parent organization had other MA contracts in November 2017, we used the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2017.

(ii) Using the enrollment in those other MA contracts as of November 2017, we calculated the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This is used as the 2021 QBP rating for the new MA contract for payment in 2021 and is released to the MA organization for the new contract in April 2020.

We explicitly explained how if there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 (for QBP purposes) and § 422.166(d)(2)(v) (for other purposes). Our proposal was to codify existing and current policy without change, and we followed these steps for the 2021 QBPs where applicable. Under this final rule, we will follow the same steps for the 2022 QBPs.

We proposed the rules for calculating the enrollment-weighted average and addressing changes in parent organizations in new paragraphs (d)(2)(iv)(C) through (E) at § 422.166. We proposed to add at § 422.166(d)(2)(vi)(C) that the enrollment used in the enrollment-weighted calculations is the November enrollment in the year the Star Ratings are released. The enrollment data are currently posted publicly at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.

We also proposed at § 422.166(d)(2)(vi)(D) that the QBP ratings would be updated for any changes in a contract's parent organization prior to the release of the final QBP ratings in April of each year. We explained that under our proposal, the same rules described at § 422.166(d)(2)(vi)(A), (B), and (C) would be applied to the new contract using the new parent organization information. We provided an example, again using the 2021 QBPs: in April 2020 when the final QBP ratings were released, the enrollment-weighted average rating would include the ratings of any MA contract(s) that the parent organization had acquired since November 2019. Thus, if a parent organization buys an existing contract it would be included in the enrollment-weighted average. We also proposed at § 422.166(d)(2)(vi)(E) to codify our current practice that once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are possible for QBP purposes.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Several commenters expressed support for codifying the QBP rating policies in regulation and provided support for the existing policies.

Response: CMS appreciates the support.

Comment: A commenter expressed concern that the QBP rating is based on too many measures and should be based on a small set of measures related to patient experience and outcomes at the geographic level.

Response: The regulation at § 422.260(b), revised in the April 2018 final rule, provides that the QBP determination methodology is the quality ratings system specified in subpart 166 of part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. The methodology for the quality ratings system was codified for the 2019 measurement year and 2021 Star Ratings in the April 2018 final rule. Further, that amendment to § 422.260(b) was merely codification of a longstanding policy, discussed in the CY 2012 proposed rule (75 FR 71219, 71221) and the CY 2012 final

rule (76 FR 21486 through 21490). We did not propose to change that rule and do not believe it is necessary or appropriate at this time.

In the April 2018 final rule, we stated that the Star Rating system provides information in a summary fashion that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care and is based on a delicate balance of measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden on the industry (83 FR 16520). Most commenters supported the principles underlying the Star Ratings program as described in the April 2018 final rule and made various suggestions for additional measure concepts to include. We do not believe that a change to the ratings used for QBP purposes is appropriate at this time and, even if we did, we believe that such a significant change from current practice as suggested in the comment should be subject to additional analysis and the opportunity for public comment via the rulemaking process. Our current Part C and D Star Ratings contractor, RAND Corporation, is currently soliciting input from their Technical Expert Panel on suggested potential changes to the mix and number of measures included in the Star Ratings program for consideration in the future. For more information about the Technical Expert Panels, please see https://www.rand.org/health-care/projects/star-ratings-analyses.html.

Comment: A couple of commenters suggested that all new contracts be treated as qualifying contracts and received the 3.5 percentage increase in the benchmark, regardless of whether the parent organization has other MA contracts. A commenter focused on this being fairer to new entrants, while another commenter focused on the statutory provision at 1857(c)(4) of the Social Security Act that guards against contracts leaving and then immediately re-entering the MA program.

Response: Historically, we have followed the rules to assign QBP ratings for a new contract under an existing parent organization that were first adopted in the 2012 Advance Notice and Rate Announcement and the April 2011 final rule that codified the definition of a new MA plan. New contracts under existing parent organizations have traditionally received the

weighted average of the ratings of the contracts under the parent organization to minimize the incentive to create new contracts to qualify for a QBP. If the overall performance of an organization is poor, that organization otherwise would have incentives to game the system to be treated as a qualifying plan for QBP purposes for 3 years. This would ignore information that CMS has about the overall performance of the contracts under the parent organization given at least some of the administrative systems are shared across contracts within a parent organization. If there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 since CMS does not have recent experience with the organization.

New contracts under existing parent organizations do not necessarily qualify for a QBP; thus, this policy is not unfair to new entrants. Additionally, new entrants where the parent organization does not have recent experience as an MA contract are treated as qualifying plans for 3 years until they have enough data to assess their performance. For the 2021 QBP ratings, 47 percent of the new contracts under existing parent organizations received 3.5 stars or less; thus, these new contracts did not qualify for QBPs. We understand that 1857(c)(4) guards against contracts leaving and immediately entering the MA program, but we believe it is still important to guard against existing contracts opening up new contracts primarily to be treated as qualifying contracts for QBP purposes.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the methodology to calculate the QBP ratings as proposed at §§ 422.162(b)(4) and 422.166(d)(2)(vi) with a slight revision of the text to further clarify that the enrollment figures used in the enrollment-weighted QBP rating calculations are the November enrollment in the year the Star Ratings are released. Our proposal was to codify existing and current policy without change, and under this final rule, we will follow the same steps as prior years for calculating the 2022 QBPs.

E. Permitting a Second, "Preferred," Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

1. Overview and Summary

Section 1860D-2(b)(2) of the Act, which establishes the parameters of the Part D program's Defined Standard benefit, allows for alternative benefit designs that are actuarially equivalent to the Defined Standard benefit, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan designs. Use of a specialty tier provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs. Our policy for the specialty tier has aimed to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority.

Section 1860D-4(g)(2) of the Act requires Part D sponsors to have an exceptions process under which a beneficiary who is enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the plan's tiered cost-sharing structure. The statute provides that under the exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if certain conditions are met. The statute grants CMS authority to establish guidelines under which Part D enrollees may request exceptions to tiered cost-sharing structures and under which a determination with respect to such a request is made. Under § 423.578(a), we require each Part D sponsor that manages its benefit through the use of a tiered formulary to establish and maintain reasonable and complete exceptions procedures subject to our approval. The Part D sponsor must grant an exception when it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement that the preferred drug: (i) would not be as effective for the enrollee as the requested drug; (ii) would have adverse effects for the enrollee; or (iii) both.

However, if Part D sponsors were to permit tiering exceptions to allow Part D enrollees to obtain drugs on specialty tiers at a lower cost sharing applicable to non-specialty tiers, they would also likely increase Part D premiums as well as cost sharing for non-specialty tiers. In other words, the ability to get lower cost sharing on specialty-tier Part D drugs through tiering exceptions means that costs would likely go up elsewhere – such as by increasing the cost sharing on generic drug tiers – in order to keep the benefit design actuarially equivalent to the Defined Standard. Consequently, in permitting Part D sponsors to maintain a specialty tier, we also implemented a regulation (most recently § 423.578(a)(6)(iii)) that permits (but does not require) Part D sponsors to exempt Part D drugs placed on the specialty tier from their tiering exceptions processes.

Accordingly, to restrict the specialty tier to only the highest-cost Part D drugs, beginning in 2007,[44,45] we developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier.[46] Additionally, to prevent discriminatory formulary structures, in particular to protect Part D enrollees with certain disease types that are treated only by specialty-tier eligible drugs, our guidance[47] has set the maximum allowable cost sharing for specialty-tier Part D drugs between 25 and 33 percent coinsurance (25/33 percent).

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[44] For 2007, we established the specialty-tier cost threshold at a negotiated price of $500 per month. Please see Medicare Modernization Act 2007 Final Guidelines – Formularies. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/cy07formularyguidance.pdf

[45] The specialty-tier cost threshold was increased to $600 per month in 2008, and remained at $600 per month from contract years 2008 through 2016. See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf and https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

[46] See, for instance, Draft 2020 Call Letter, pages 178-179 (available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf), and Final 2020 Call Letter, page 208 (available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf).

[47] See section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf and page 21 of the 2020 Bid Submission User Manual, Chapter 7: Plan Benefit Package Rx Drugs Section. The Bid Submission User Manual for 2020 is available at the following pathway after logging into the Health Plan Management System (HPMS): Plan Bids > Bid Submission > Contract Year 2020 > View Documentation > Bid Submission User Manual.

We have not previously permitted Part D sponsors to structure their plans with more than one specialty tier. Pointing to factors such as the introduction of biosimilar biological products to the market[48] and recent higher pricing of some generic drugs relative to brand drug costs, some stakeholders requested that we reconsider this policy. They posited, for instance, that creating an additional specialty tier could improve the ability of Part D sponsors to negotiate with pharmaceutical manufacturers to help lower the prices of high-cost Part D drugs. Moreover, in its June 2016 Report to Congress (available at http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf), the Medicare Payment Advisory Commission (MedPAC) suggested that allowing plans to maintain two specialty tiers with differential cost sharing could potentially encourage the use of lower-cost biosimilar[49] biological products and encourage competition among existing specialty Part D drugs. More recently, some commenters on our Draft 2020 Call Letter (available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf) took the opportunity to advocate for a second specialty tier.

Improving Part D enrollee access to needed drugs and lowering drug costs are central goals for CMS. Accordingly, in the hopes of providing flexibility that will promote these goals, we proposed to allow (but not require) Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. Under this policy, Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the specialty-tier cost threshold that would be established according to the methodology we proposed and the requirements of our formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we proposed to codify a maximum allowable cost sharing that would apply to a

[48] See the April 2018 final rule for more background on biosimilar biological products (83 FR 16610).
[49] Unless our policy specifically distinguishes biosimilar biological products from interchangeable biological products, we use the term "biosimilar biological product(s)" in this preamble to reference biosimilar or interchangeable (when such products become available) biological products.

single specialty tier, or, if a Part D sponsor has a plan with two specialty tiers, to the higher cost-sharing, specialty tier. Further, we proposed to require that if a Part D sponsor has a plan with two specialty tiers, one must be a "preferred" tier that offers lower cost sharing than the higher cost-sharing, specialty tier.

We note that we did not propose any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a Part D drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. The exemption from tiering exceptions for specialty-tier Part D drugs, at § 423.578(a)(6)(iii), would apply only to tiering exceptions to non-specialty tiers (meaning, when the tiering exception request is for the specialty-tier Part D drug to be covered at a cost-sharing level that applies to a non-specialty tier). Under our proposal, we would require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing, specialty tier to the lower cost-sharing, specialty tier.

To improve transparency, we proposed to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we proposed to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, inclusive (that is, 25 percent $\leq$ maximum allowable cost sharing $\leq$ 33 percent), depending on whether the plan includes a deductible, as described further in section IV.E.4. of this final rule.

We also proposed to determine the specialty-tier cost threshold – meaning whether the drug has costs high enough to qualify for specialty-tier placement – based on a 30-day equivalent supply. Additionally, we proposed to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the PDE. This would be a change from our current policy, which uses the negotiated price reflected on the PDE. Under our proposal, the specialty-tier cost threshold would apply to both specialty tiers.

To respond to comments on our Draft 2020 Call Letter requesting that the specialty-tier cost threshold be increased regularly, we also proposed to maintain a specialty-tier cost threshold

that is set at a level that, in general, reflects Part D drugs with monthly ingredient costs that are in the top 1 percent of all monthly ingredient costs, as described further in section IV.E.6. of this final rule. We proposed to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDEs shows that recalibration of the specialty-tier cost threshold is necessary to continue to reflect only Part D drugs with the top 1 percent of monthly ingredient costs. We proposed to annually: (1) determine whether the adjustment would be triggered, and (2) announce the specialty-tier cost threshold.

2. A Second, "Preferred," Specialty Tier

Placement on the specialty tier can play an important role in maintaining lower cost sharing on non-specialty tiers. The non-specialty, non-preferred brand/drug tiers frequently have cost sharing equal to as much as 50 percent coinsurance. This means that Part D enrollees would pay considerably more after application of coinsurance for a high-cost drug if it appeared on a non-specialty, non-preferred brand/drug tier with, for instance, 50 percent cost sharing as opposed to placement on the specialty tier, which has been subject to lower cost-sharing requirements. For this reason, we reject the recommendation of some commenters on our Draft 2020 Call Letter that we eliminate the specialty tier altogether.

To the opposite effect, as discussed in section IV.E.1 of this final rule, other stakeholders, including MedPAC, have recommended that we permit Part D sponsors to maintain a second specialty tier. Stakeholders favoring this approach have posited that this change would: (1) improve the ability of Part D sponsors and pharmacy benefit managers (PBMs) to negotiate better rebates[50] with manufacturers by enabling them to establish a preferred specialty tier that distinguishes between high-cost drugs and effectively encourages the use of preferred specialty-tier Part D drugs; (2) reduce costs for Part D enrollees, not only through direct cost-sharing savings associated with a lower cost-sharing, "preferred" specialty tier, but also indirectly,

[50] In this section of this final rule, by "rebates," we are broadly referring to either retrospective or point-of-sale (POS) rebates or discounts.

through the lowered premiums for all Part D enrollees that could result from better rebates on specialty-tier Part D drugs; and (3) reduce our costs directly through lower drug costs because lower cost sharing would delay a Part D enrollee's entry into the catastrophic phase of the benefit in which the government is responsible for 80 percent of the costs.

Consistent with our ongoing efforts to implement new strategies that can help lower drug prices and increase competition, we proposed to permit Part D sponsors to have up to two specialty tiers by permitting a new preferred specialty tier. However, driven by ongoing concerns over actuarial equivalence and discriminatory benefit designs, in order to strike the appropriate balance between plan flexibility and Part D enrollee access, we also needed to carefully weigh the following factors: (1) tiering exceptions between the two specialty tiers or to other, non-specialty tiers; (2) the maximum allowable cost sharing for each specialty tier; and (3) tier composition (that is, the selection of Part D drugs for each specialty tier). The regulatory text to allow up to two specialty tiers (which reflects our consideration of these factors) and other related proposals are discussed in the following sections of this preamble.

We received 82 public comments concerning our proposal to permit Part D sponsors to maintain up to two specialty tiers. Although there was some overlap in stakeholder categories, 81 comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. The remaining comment was from an individual beneficiary. A summary of the comments and our responses follow.

Comment: Many commenters supported CMS's proposal.

Response: We thank the commenters for their support.

Comment: Some commenters advocated that CMS should abolish specialty tiers altogether, finding them to be outdated and discriminatory to the Part D enrollees whose conditions require they take Part D drugs placed on the specialty tiers. Similarly, these commenters suggested that specialty tiers are unique to prescription drug benefits with no

equivalent in the medical benefit and run counter to the purpose of insurance altogether by effectively serving as what the commenter termed "reverse insurance," reasoning that the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit.

Response: We thank the commenters for this perspective. However, the use of specialty tiers in the commercial market predates the Part D program by several years, and there is widespread use of two specialty tiers in employer-based plans, with some plans using two or more specialty tiers since at least 2014.[51,52,53,54,55,56,57] Additionally, Part D enrollee cost sharing for the specialty tier(s) in Part D, with a maximum allowable cost sharing of 25/33 percent coinsurance is equal to, or, in the case of the preferred, specialty tier that has cost sharing less than the 25/33 percent maximum, better than cost sharing under the Defined Standard benefit. Because cost sharing under the Defined Standard benefit is provided for by statute, neither cost sharing under the Defined Standard benefit nor specialty-tier cost sharing, which is better than the Defined Standard benefit, is discriminatory. Moreover, a hallmark of Medicare Part D is that it relies on market forces to provide prescription drug benefits to Part D enrollees, and, as a public benefit that is administered by the private insurance market, it is incumbent upon us to keep abreast of industry standards for the provision of this benefit while also balancing Part D enrollee access to prescription drugs. While the use of a specialty tier may be counterintuitive, it is a tool widely used in the industry to address a highly volatile market for high-cost Part D

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[51] The following link provides access to the Kaiser Family Foundation's archives of the annual Employer Health Benefits Survey. https://www.kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/
[52] Kaiser Family Foundation 2014 Employer Health Benefits Annual Survey, Pages 164 and 166, http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report
[53] Kaiser Family Foundation 2015 Employer Health Benefits Annual Survey, Pages 160-162, http://files.kff.org/attachment/report-2015-employer-health-benefits-survey
[54] Kaiser Family Foundation 2016 Employer Health Benefits Annual Survey, Pages 172-174, http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey
[55] Kaiser Family Foundation 2017 Employer Health Benefits Annual Survey, Page 156, http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017
[56] Kaiser Family Foundation 2018 Employer Health Benefits Annual Survey, Page 161, http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018
[57] Kaiser Family Foundation 2019 Employer Health Benefits Annual Survey, Page 161, http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019

drugs. Although there are distinctions between commercial plans and the Medicare Part D program, we believe this particular option is worth pursuing, not only because of the possibility that benefits could ensue, but most centrally because we do not anticipate that permitting a second, preferred specialty tier would lead to additional harms for Part D enrollees given our proposed Part D enrollee protections, such as retention of the 25/33 percent maximum allowable cost sharing.

We also disagree with the assertion that the specialty tier(s) serve as a perverse, "reverse insurance" whereby the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit. We believe this reasoning is flawed because the specialty tier is aligned with the Defined Standard benefit, and the Part D plan bid requirements also necessitate that the benefit structure below the specialty tier also be actuarially equivalent to the Defined Standard benefit. Therefore, the use of specialty-tier eligible drugs has no differential impact on lowering the premiums and cost sharing on non-specialty tiers for the rest of the benefit.

Lastly, we believe that providing Part D sponsors the ability to make business decisions regarding the distribution of insurance risk, as permitted by the statute and while retaining central Part D enrollee protections, reflects the goals of the Part D program, which aim to provide flexibilities, when possible, that could enable Part D sponsors to offer robust formularies with lower costs.

Comment: Some commenters expressed concern that, although CMS proposed to permit Part D sponsors to maintain up to two specialty tiers, CMS did not propose corresponding regulatory text to this effect. Some commenters urged CMS to clarify that a second specialty tier is voluntary, and other commenters urged CMS to clarify that a second specialty tier would be in addition to the total number of allowed drug tiers, rather than in place of an existing tier.

Response: We proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers; additionally, as discussed in section IV.E.3

of this final rule, we also proposed to amend § 423.578(a)(6)(iii) to reflect the possibility of a second specialty tier. Maintaining one or two specialty tier(s) is voluntary. Similarly, we also clarify that a second specialty tier would be in addition to, not in lieu of, the six existing tiers for actuarially equivalent benefit designs.

Comment: Some commenters suggested that this proposal would limit access to specialty-tier Part D drugs, complicate an already complicated benefit structure / process for Part D enrollees, and/or would involve additional, burdensome utilization management for prescribers. Some commenters urged CMS to do a demonstration or pilot before finalizing the proposals to permit a second specialty tier, while others urged CMS to monitor the uptake of the use of a second specialty tier.

Response: We do not anticipate adverse effects to Part D enrollees' access to specialty-tier Part D drugs by allowing Part D sponsors to structure their benefits with a second, "preferred" specialty tier, as we have proposed, either in terms of formulary access or Part D enrollee cost sharing. This is due in large part to the other Part D enrollee protections we proposed in conjunction with our proposal to permit Part D sponsors to maintain a second specialty tier (notably, tiering exceptions between the two specialty tiers and maximum allowable cost sharing, as discussed in sections IV.E.3., and IV.E.4., respectively, of this final rule). As we do not anticipate that permitting a second, preferred specialty tier would lead to harm for any Part D enrollees, it seems reasonable to provide the requested flexibility, as proposed, to Part D sponsors. We are mindful of the need to minimize complexity and make our rules as transparent as possible. However, we believe that the risk of confusion will be outweighed by the potential for Part D sponsors to provide their enrollees with improved access to specialty-tier Part D drugs because improved competition for preferred specialty tier formulary placement results in better negotiations for Part D sponsors, which could result in lower cost sharing for Part D enrollees.

Many specialty-tier Part D drugs already require utilization management, including prior authorization and/or step therapy to access the drug, and then monitoring the enrollee once therapy has been initiated. Utilization management requirements are subject to the requirements of our annual formulary review and approval process under § 423.120(b)(2). (We detailed the components of our annual formulary review and approval process in our May 2019 final rule (84 FR 23835).) As part of this review and approval process, we perform multiple reviews related to the clinical appropriateness of both tier composition and utilization management strategies. For additional information, please also see section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.) Additionally, the same specialty-tier cost threshold would apply to both specialty tiers. In other words, there is no difference in eligibility for specialty-tier placement between the two specialty tiers, and therefore, specialty-tier eligible Part D drugs would be divided between the two specialty tiers. Consequently, we do not anticipate that allowing a second specialty tier would introduce significant utilization management beyond what is already required or increase the number of drugs placed on a specialty tier.

In finalizing our proposals to permit Part D sponsors to maintain up to two specialty tiers, we intend to monitor the uptake of the use of a second specialty tier. We are unclear about, generally, what the commenters believe we would research in a demonstration or pilot, and do not believe one is necessary given the Part D enrollee protections we are finalizing as part of this final rule.

Comment: Some commenters suggested that CMS should not finalize the proposals regarding permitting Part D to maintain up to two specialty tiers for 2021 and that CMS should clarify that the bids for coverage year 2021 will be based on existing rules. Some commenters mentioned that CMS needs to issue new guidance regarding the Plan Bid Package (PBP) Beta Software, which currently does not provide the functionality to file a preferred specialty tier, and

that to maintain compliance, CMS needs to provide the specific filing requirements for the second tier. Some commenters suggested that with these changes, CMS must continue to improve written and online materials to provide clear, unbiased, user-friendly language and graphics, and engage in public campaigns to inform and educate Part D enrollees and their caregivers about benefit designs and cost sharing obligations. Some commenters suggested that if CMS finalizes our proposals to permit Part D sponsors to maintain up to two specialty tiers, that CMS will need to "recodify" guidance in the "Coverage Determination Manual." Some commenters suggested that CMS should institute a generic / biosimilar utilization Star ratings measure focused on specialty-tier drugs.

Response: The proposals regarding permitting Part D sponsors to maintain up to two specialty tiers that are being finalized in this rulemaking will be in effect for coverage year 2022. Additionally, we intend to issue program instructions regarding the filing of two specialty tiers in the Contract Year (CY) 2022 Part D Bidding Instructions. In the May 22, 2020 HPMS memo titled, "Updated Contract Year (CY) 2021 Final Part D Bidding Instructions," we instructed that bids for coverage year 2021 will be based on existing rules for the specialty tier. We continue to regularly review our policies regarding marketing and other communication materials and expect Part D sponsors to follow the requirements that are being finalized elsewhere in this final rule. Although we assume the commenters referring to the "Coverage Determination Manual" meant our Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf, we are not clear on what the commenters believe needs to be "re"-codified, and welcome further input on this matter. In our Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (available at https://www.cms.gov/files/document/2021-announcement.pdf), we discussed the

potential to develop measures to assess generic and biosimilar utilization in the Medicare Part D program, and we continue to review feedback for a potential future measure.

We are finalizing without modification our proposals to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers. The proposals regarding permitting Part D sponsors to maintain up to two specialty tiers that are being finalized in this rulemaking will apply for coverage year 2022.

To retain the policies in effect before coverage year 2022, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will be in effect before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase "and biological products," and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

3. Two Specialty Tiers and Tiering Exceptions

As discussed in section IV.E.1. of this final rule, section 1860D-4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the Part D sponsor's tiered cost-sharing structure. Additionally, Part D sponsors are required under this section of the statute to create an exceptions process to handle such requests, consistent with guidelines we established (see section 40.5.1 of Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf). However, section 1860D-4(g)(2) of the Act does not require tiering exceptions in every case, and rather, indicates that tiering exceptions

might not be covered in every instance, by recognizing that non-preferred Part D drugs "could" be covered at the cost sharing applicable to preferred Part D drugs.

As discussed in section IV.E.1. of this final rule, the requirement that Part D plans be actuarially equivalent to the Defined Standard benefit means that if Part D sponsors were required to permit Part D enrollees to obtain Part D drugs on specialty tiers at non-specialty-tier cost sharing, Part D sponsors might need to increase premiums, cost sharing for non-specialty tiers, or both. To avoid such increased costs, in the Medicare Program; Medicare Prescription Drug Benefit Final Rule (hereinafter referred to as the January 2005 Part D final rule, 70 FR 4193), we finalized § 423.578(a)(7), which provided that Part D sponsors with a tier for very high cost and unique items, such as genomic and biotech products (in other words, a specialty tier), could exempt such drugs from its tiering exception process (70 FR 4353). In our April 2018 final rule, we revised and redesignated § 423.578(a)(7) as § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains a specialty tier, the Part D sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for tiering exceptions. While the current policy does not require that Part D sponsors use a specialty tier, or exempt the drugs on such tier from tiering exceptions, nearly all do use a specialty tier and also exempt the drugs on such tier from tiering exceptions.

Section 1860D-4(g)(2) of the Act stipulates that under a tiering exception, a non-preferred Part D drug could be covered under the terms applicable for preferred Part D drugs if the prescriber determines that the preferred Part D drug for treatment of the same condition would not be as effective for the Part D enrollee, would have adverse effects for the Part D enrollee, or both. Thus, the statutory basis for approval of tiering exceptions requests is the presence of (a) clinically appropriate, therapeutically alternative Part D drug(s) on a lower cost-sharing tier of the plan's formulary, and a statement from the prescriber indicating that the alternative drug(s) would not be as effective for that enrollee or would cause adverse effects for the enrollee, or both. Therefore, even if a Part D sponsor permitted tiering exceptions for Part D

drugs on the specialty tier to non-specialty tiers, tiering exceptions requests would not be approvable if the plan's formulary did not include any clinically appropriate, therapeutically alternative Part D drugs on a lower cost-sharing tier. For example, suppose that a biological product, "Biologic A," and another biological product that is indicated for the same condition, "Biologic B," are both on the specialty tier with no clinically appropriate, therapeutically alternative Part D drugs on a lower cost-sharing tier. If the Part D enrollee's prescriber were to write a prescription for Biologic A, and the prescriber were to request a tiering exception, because Biologic B, the clinically appropriate therapeutic alternative, is on the same tier as Biologic A, and not a lower cost-sharing tier, the tiering exception request would be denied. For further explanation of tiering exceptions requirements, please see § 423.578(a)(6).

Permitting Part D sponsors to exempt Part D drugs on a higher cost-sharing, specialty tier from any tiering exceptions, even to a lower cost-sharing, preferred specialty tier, could improve Part D sponsors' ability to negotiate better rebates. Nevertheless, unlike our justification for allowing Part D plans to exempt a specialty tier from tiering exceptions to lower-cost, non-specialty tiers, granting tiering exceptions from the higher cost-sharing, specialty tier to the preferred specialty tier is less likely to lead to increased premiums or cost sharing to meet actuarial requirements (than granting tiering exceptions from a specialty tier to a non-specialty tier) because we would apply the same specialty-tier cost threshold to both specialty tiers. Our current belief is that improved negotiation alone is not sufficient to justify permitting Part D sponsors to exempt drugs on the higher cost-sharing, specialty tier from requests for tiering exceptions to the preferred, specialty-tier cost sharing. We note that we did not propose to require Part D sponsors to permit tiering exceptions from either specialty tier to lower, non-specialty tiers, and our policy would not change current regulations at § 423.578(c)(3)(ii) that require Part D sponsors to cover drugs for which a tiering exception was approved at the cost-sharing level that applies to the preferred alternative(s). This means that Part D sponsors would be required to grant tiering exceptions for Part D drugs from the higher cost-sharing, specialty

tier to the preferred specialty tier if tiering exceptions requirements are met (for instance, when a Part D enrollee cannot take an applicable therapeutic alternative on the preferred specialty tier). Specifically, we proposed to amend § 423.578(a)(6)(iii) (1) to reflect the possibility of two specialty tiers and (2) by adding at the end the phrase "to non-specialty tiers" to clarify that a Part D sponsor may design its tiering exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exceptions to non-specialty tiers. Consequently, the existing policy at § 423.578(c)(3)(ii) would require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. While we would not require Part D sponsors to permit tiering exceptions to non-specialty tiers for Part D drugs on a specialty tier, nothing precludes a Part D sponsor from doing so, insofar as their plan benefit design remains actuarially equivalent to the Defined Standard benefit.

Alternatively, we considered permitting Part D sponsors to exempt drugs on either specialty tier from all tiering exceptions, even between the two specialty tiers, as is provided under the existing regulations at § 423.578(a)(6)(iii). We do not believe maintaining the current exemption would be discriminatory in light of our proposal, discussed in section IV.E.4 of this final rule, to set the same maximum allowable cost sharing (that is, 25/33 percent) currently applied for a single specialty to-the higher cost-sharing, specialty tier and to also require the preferred specialty tier to have cost sharing below that of the higher cost-sharing, specialty tier. With the proposed maximum allowable cost sharing, Part D enrollees would pay no more for a drug on either specialty tier than is the case under our current policy. And, as noted previously, maintaining the current exemption from all tiering exceptions for specialty-tier Part D drugs could allow Part D sponsors to negotiate better rebates. On the other hand, our proposal to require Part D sponsors with two specialty tiers to permit tiering exceptions from the higher cost-sharing, specialty tier to the lower-cost sharing, preferred specialty tier would provide an

important Part D enrollee protection when there is a therapeutic alternative on the lower cost-sharing, preferred specialty tier that the Part D enrollee is unable to take. Accordingly, we invited comment on the benefits or drawbacks of maintaining the current policy under § 423.578(a)(6)(iii) that, if we were to finalize our proposal to permit Part D sponsors to have up to two specialty tiers, would apply to permit Part D sponsors to exempt drugs on a specialty tier from the tiering exceptions process altogether.

We note that, as part of our proposed change at § 423.578(a)(6)(iii), we also proposed a technical change to remove the phrase "and biological products." While the specialty tier usually includes biological products, in the context of the Part D program, biological products already are included in the definition of a Part D drug at § 423.100. Therefore, the phrase "Part D drugs and biological products" is redundant and potentially misleading. Consequently, we proposed to remove the phrase "and biological products."

To summarize, we proposed to amend § 423.578(a)(6)(iii) to: (1) reflect the possibility of a second specialty tier, (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers, and (3) remove the phrase "and biological products." Additionally, we proposed to maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, although contingent on finalizing our proposal to permit Part D sponsors to maintain up to two specialty tiers, we solicited comment on maintaining the existing policy at § 423.578(a)(6)(iii), thereby permitting Part D sponsors to exempt drugs on either specialty tier from the tiering exceptions process altogether.

We received 35 public comments concerning our proposal to require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage (for the approved Part D drug on the higher cost-sharing, specialty tier) at the cost-sharing level that applies to the

preferred alternative Part D drug on the lower cost-sharing, preferred specialty tier, and 32 public comments concerning our proposal that Part D sponsors can extend to both specialty tiers their current ability to design their exceptions processes to exempt Part D drugs on the specialty tier from tiering exceptions to non-specialty tiers (while requiring tiering exceptions between the two specialty tiers). We received 9 public comments concerning the alternative on which we solicited comment to permit Part D sponsors to design their exceptions processes to exempt drugs on either specialty tier from the tiering exceptions process altogether.

We received no comments on our proposal to amend § 423.578(a)(6)(iii) by removing the phrase "and biological products" and therefore are finalizing this provision without modification.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Many commenters supported CMS's proposals. However, some commenters opposed CMS's proposal that Part D sponsors be permitted to design their exceptions processes to exempt Part D drugs on the specialty tiers(s) from tiering exceptions to non-specialty tiers (while requiring tiering exceptions between the two specialty tiers) and also opposed the alternative on which CMS solicited comment to permit Part D sponsors to design their exceptions processes to exempt drugs on either specialty tier from the tiering exceptions process altogether. Some of these commenters, in advocating that CMS require tiering exceptions from the specialty tiers to the non-specialty tiers, found any exemption of the specialty tiers from tiering exceptions to be both discriminatory and a violation of Part D enrollees' statutory rights. Some commenters believed that CMS's proposals and the alternative on which CMS solicited comment prohibited Part D sponsors from offering tiering exceptions.

Response: We thank the commenters who supported our proposals for their support. We disagree that permitting Part D sponsors to design their exceptions processes to exempt Part D

drugs on the specialty tier(s) from tiering exceptions to the non-specialty tiers is discriminatory or a violation of Part D enrollees' statutory rights.

Since the beginning of the Part D program, as reflected in our January 2005 Part D final rule, it has been our policy to permit Part D plans to exempt drugs on the specialty tier from tiering exceptions. We did not propose to change this exemption, but rather to adapt it to the possibility of a plan's having two specialty tiers. Historically, the specialty tier has aligned with the Defined Standard benefit, which does not have tiers, and therefore no tiering exceptions. The alignment with the Defined Standard benefit meant that an enrollee's cost sharing for a specialty tier drug would not exceed what would otherwise apply under the Defined Standard benefit, and that tiering exceptions similarly would not be available. We disagree with commenters that exempting the specialty tier(s) from tiering exceptions to non-specialty tiers is discriminatory precisely because of its alignment with the Defined Standard benefit, which, as previously noted, has no tiers, and therefore no tiering exceptions. Moreover, by the same rationale, we do not believe that permitting Part D sponsors to design their exceptions processes to exempt Part D drugs on the specialty tier(s) from tiering exceptions to non-specialty tiers violates a Part D enrollee's rights. As noted earlier, we believe section 1860D-4(g)(2) of the Act does not require tiering exceptions in every case. The addition of a second, preferred specialty tier does not change this analysis, particularly in light of the parameters we are finalizing (described elsewhere in this rule) that cap specialty tier cost sharing at the level that remains aligned with the Defined Standard benefit.

In response to comments regarding whether Part D sponsors should be required to permit tiering exceptions request from the higher-cost specialty tier to the lower-cost specialty tier, we are finalizing our proposal, and not adopting the alternative we considered. We continue to believe that a Part D drug's placement on a specialty tier can play an important role in maintaining lower cost sharing on non-specialty tiers, and we must balance the ability to get lower cost sharing on specialty-tier Part D drugs through tiering exceptions with the requirement

that plans be actuarially equivalent to the Defined Standard benefit. Consequently, while we are not changing our policy that permits Part D sponsors to exempt drugs from tiering exceptions between the specialty and non-specialty tiers, as was originally envisioned by § 423.578(a)(6)(iii), we believe that requiring Part D sponsors to design their tiering exceptions processes to permit tiering exceptions between the two specialty tiers, as provided at § 423.578(c)(3)(ii), strikes the appropriate balance.

Finally, we wish to clarify that Part D sponsors are not required to have a specialty tier at all, and under the provisions we are finalizing, can choose one, two, or no specialty tier(s). Similarly, Part D sponsors are not required to permit tiering exceptions from a specialty tier to a non-specialty tier. However, Part D sponsors also are permitted to design their tiering exceptions processes in such a way as to permit these tiering exceptions from a specialty tier to a non-specialty tier if they wish, so long as the plan's benefit design remains actuarially equivalent to the Defined Standard benefit.

We are finalizing without modification our proposals to amend § 423.578(a)(6)(iii) to: (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers. Additionally, the existing policy at § 423.578(c)(3)(ii) applies as to the two specialty tiers, meaning that Part D sponsors must permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier at the cost sharing that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, we intend to monitor the uptake of the use of a second specialty tier, and may revisit our decision to require plans to allow tiering exceptions between the two specialty tiers in future rulemaking.

Comment: Some commenters suggested that specialty tiers and tiering exceptions have no clinical basis. They reasoned that, because of this, CMS should define several terms (such as "specialty drug." and "specialty pharmacy") and provide additional clinical guidance for Part D

sponsors when implementing a second specialty tier. Other commenters added that CMS should delay implementation of CMS's proposals to permit two specialty tiers in order to undertake further rulemaking to refine CMS's proposal with additional details regarding clinically based Part D enrollee protections.

Response: We acknowledge that we have based a Part D drug's eligibility for placement on the specialty tier on whether such Part D drug meets the dollar-per-month amount of the specialty-tier cost threshold. However, our application of the tiering exceptions policy has been, and remains, rooted in a clinical basis. To illustrate, while the specialty tier in Part D is limited to the highest-cost Part D drugs, these drugs are often relatively more structurally complicated, and apply to complex conditions, including, but not limited to, cancer, Hepatitis C, HIV/AIDS, Multiple Sclerosis, and Rheumatoid Arthritis. Section 1860D-4(g)(2) of the Act specifies that under a tiering exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescriber determines that the preferred drug (for treatment of the same condition) would not be as effective for the individual, would have adverse effects for the individual, or both. Therefore, tiering exceptions always have a clinical basis, and requiring tiering exceptions between the two specialty tiers reinforces the clinical deliberations Part D sponsors must undertake when considering formulary inclusion and tier composition with regard to specialty-tier Part D drugs. Because the pharmacy practice landscape is changing so rapidly, and because the considerations are so varied, we continue to believe that any attempt by us to define "specialty drug" or "specialty pharmacy" is not warranted at this time. Nonetheless, throughout this final rule, we have opted to use the term "specialty-tier drug" instead of "specialty drug" in order to clarify that our discussion is limited to drugs which meet specialty-tier cost threshold and are therefore eligible for inclusion on a specialty tier in Part D.

Comment: Some commenters stated that the tiering exceptions process is confusing for Part D enrollees, and suggested that CMS should eliminate tiering exceptions altogether. Other commenters provided that permitting tiering exceptions between the specialty tiers but not to

non-specialty tiers would be confusing to Part D enrollees. Some of these commenters suggested that CMS should allow tiering exceptions from the specialty to the non-specialty tiers, while others suggested that CMS should require tiering exceptions from the specialty to the non-specialty tiers.

Response: We are mindful of the need to minimize complexity and make our rules as transparent as possible. We appreciate the commenters' perspectives and welcome further detail on both the difficulties that Part D enrollees encounter during the exceptions and appeals process as well as any changes to our marketing and communications materials that could better address these difficulties.

However, we believe that any additional complexity arising from permitting a second specialty tier will be outweighed by the potential to improve enrollee access to specialty-tier Part D drugs. We did not propose to change our policy that permits Part D sponsors to exempt a specialty tier from tier exceptions to a non-specialty tier. Section 1860D-4(g)(2) of the Act provides that Part D enrollees may request exceptions from tiered cost-sharing structures. For this reason, we decline to either eliminate tiering exceptions altogether or require Part D sponsors to permit tiering exceptions from the specialty tiers to the non-specialty tiers. Regarding the request that we should allow tiering exceptions from the specialty to the non-specialty tiers, we note that this is already permitted under § 423.578(a)(6)(iii), and Part D sponsors will continue to have this option under the finalized version of this regulation.

Comment: Some commenters suggested that Part D enrollees who have undergone step therapy, failed other therapies, won a coverage determination or appeal, or a combination of the above, should have non-specialty, preferred cost sharing.

Response: While we appreciate the commenters' perspectives, we did not propose, and decline to adopt, these changes. For further explanation of tiering exceptions requirements and the associated cost sharing, please see § 423.578(a)(6) and section 40.5.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (available

at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf).

Additionally, section 40.5.2 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance discusses the parameters for cost sharing under formulary exceptions. Unlike under the tiering exceptions regulations, the regulations do not specify what level of cost sharing applies when an exception is approved under the formulary exceptions process. Rather, the regulations at § 423.578(b)(2)(iii) require that the plan's formulary exceptions process must address the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

Comment: Some commenters suggested CMS could use CMS's annual formulary review and approval process to prevent discriminatory plan benefit designs, although some commenters asserted CMS has not been transparent about how it conducts the discrimination review. Some commenters suggested that CMS should exempt the specialty tiers from the discrimination review altogether, and some suggested that CMS's formulary review and approval process should evaluate both tiers as a whole instead of each tier independently. Finally, some commenters asserted that additional discrimination reviews on higher specialty tier will lead to more exception requests and thus additional administrative burden for plan sponsors.

Response: As we discussed in our final rule, titled "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," published in the Federal Register on May 23, 2019 (hereinafter referred to as our May 2019 final rule, 84 FR 23835), our annual formulary review and approval process is designed to ensure that Part D formularies do not substantially discourage enrollment by certain beneficiaries and that the formularies include adequate representation of all necessary Part D drug categories or classes for the Medicare population. In other words, our annual formulary review and approval process is designed to prevent discriminatory plan benefit designs. As part of that review and approval process, we assess all tiers both individually and together for the formulary as a whole, and that

approach will continue with respect to plans that choose to establish two specialty tiers. Please see our May 2019 rule for additional detail on the components of the annual formulary review and approval process (84 FR 23835). Finally, although we do not understand the commenters' assertion that additional discrimination reviews on the higher cost-sharing, specialty tier will lead to more exception requests and thus additional administrative burden, we welcome additional detail on this issue for consideration in future rulemaking.

Comment: Some commenters suggested that CMS should review all tiering exceptions requests after implementation. Some commenters requested that CMS enforce the existing exceptions and appeals processes.

Response: We monitor and enforce the requirements of our coverage determinations and appeals processes, including tiering exceptions, through the Complaints Tracking Module (CTM), regional CMS account managers, Part D reporting requirements, and program audits. (See https://www.cms.gov/files/document/cy2020part-d-reporting-requirements082719.pdf for more detail about reporting requirements.) Additionally, in recent years, we have undertaken efforts to improve our exceptions and appeals processes, including improving clarity of the exceptions timeframes for Part D drugs. (See our final rule, titled "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for years 2020 and 2021," published in the Federal Register on April 16, 2019, hereinafter referred to as our April 2019 rule, 84 FR 15777). We appreciate the commenters' perspectives and welcome further detail on both the difficulties that Part D enrollees encounter during the exceptions and appeals processes as well as any changes to our marketing and communications materials that could better address these difficulties.

We are finalizing without modification our proposals to amend § 423.578(a)(6)(iii) to: (1) reflect the possibility of a second specialty tier, (2) clarify that Part D sponsors may design their

exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers, and (3) remove the phrase "and biological products." Additionally, we will maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier.

4. Two Specialty Tiers and Maximum Allowable Cost Sharing

At the start of the Part D program, although we provided Part D sponsors the option to exempt specialty tiers from the tiering exceptions process, we remained concerned that exempting the specialty tier from tiering exceptions could potentially be discriminatory for Part D enrollees with certain diseases only treated by specialty tier-eligible drugs, and thus in conflict with the statutory directive under section 1860D-11(e)(2)(D) of the Act that we disapprove any "design of the plan and its benefits (including any formulary and tiered-formulary structure) that are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." Using this authority, we aligned the cost-sharing limit for Part D drugs on the specialty tier with the Defined Standard benefit at section 1860D-2(b)(2)(A) of the Act. Consequently, we established a "25/33 percent" maximum allowable cost sharing for the specialty tier, meaning that we would approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL (that is, 25 percent $\leq$ maximum allowable cost sharing $\leq$ 33 percent). In other words, under actuarially equivalent alternative prescription drug coverage designs, we allow the maximum allowable cost sharing for the specialty tier to be between 25 and 33 percent coinsurance, inclusive, if the Part D plan has a decreased deductible, such that the maximum allowable cost sharing equates to 25 percent coinsurance plus the standard deductible. We derived the maximum allowable cost sharing of 33 percent coinsurance for plans with no

deductible under alternative prescription drug coverage by adding the allowable deductible to the 25 percent maximum allowable cost sharing between the deductible and initial coverage limit (ICL) and dividing the resultant value by the ICL. The following calculations illustrate how we derived the maximum allowable cost sharing for the specialty tier.

a. Derivation of 33 percent maximum allowable cost sharing for plans with no deductible.

In 2006, under the Defined Standard benefit, the maximum deductible was $250, and the ICL was $2250. The maximum allowable cost sharing between the deductible and the ICL was, as it is today, 25 percent coinsurance. (This example uses contract year 2006 numbers for simplicity, but the concepts presented still apply to current guidance.)

$2250 ICL – $250 deductible = $2000 difference x 0.25 = $500 maximum allowable cost sharing after the deductible and before the ICL for specialty-tier Part D drugs in plans with the standard deductible.

$500 maximum (previous calculation) + $250 deductible = $750 maximum for plans with no deductible.

Therefore, the maximum allowable coinsurance before the ICL for specialty-tier Part D drugs in plans with no deductible is $750 divided by the $2250 ICL ≈ 0.33, or 33 percent coinsurance.

b. Derivation of maximum allowable cost sharing for plans with deductible between $0 and the maximum deductible.

Plans with deductibles between $0 and $250 are permitted to have maximum allowable cost sharing for specialty-tier Part D drugs between the deductible and the ICL of between $500 and $750 (that is, coinsurance between 25 and 33 percent, inclusive) provided that such cost sharing added to the deductible is $750.

For example, using contract year 2006 numbers, if the deductible was $100, the maximum coinsurance that the plan could charge for specialty-tier Part D drugs between the deductible and the ICL would have been approximately 30 percent:

$750 - $100 deductible = $650 maximum allowable cost sharing (that is, $650 + $100 = $750).

$2250 ICL - $100 deductible = $2150 difference

$650 divided by $2150 ≈ 0.30, or 30 percent

Therefore, the maximum allowable coinsurance between the $100 deductible and the $2250 ICL ≈ 0.30, or 30 percent coinsurance. (This 30 percent represents mathematical rounding from the actual calculated value.)

Because section 1860D-2(b)(2) of the Act requires that plan benefit designs be actuarially equivalent to the Defined Standard benefit, the cost sharing for high-cost drugs would likely increase without the use of a specialty tier. This is because often the specialty tier has lower cost sharing than the non-specialty, non-preferred brand/drug tiers, which frequently have cost sharing as much as 50 percent coinsurance. Additionally, many specialty tier-eligible Part D drugs, particularly biological products, often do not have alternatives on lower-cost tiers. Our proposal to codify a maximum allowable cost sharing for the specialty tier equal to the cost sharing for the Defined Standard benefit plus the cost of any deductible would ensure Part D enrollees still pay no more than the Defined Standard cost sharing for high-cost drugs placed on a specialty tier.

Although we proposed to allow Part D sponsors to have up to two specialty tiers, we note that the currently available tier-model structures already allow Part D sponsors to negotiate rebates and distinguish their preferred, high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier. Such distinction could potentially drive the same rebates as two specialty tiers; however, Part D sponsors have told us they are reluctant to take such an approach because of the availability of tiering exceptions for the non-specialty tiers, which could increase costs in lower, non-specialty tiers in order to achieve actuarial equivalence. We believe this concern is addressed by our

proposal (discussed in section IV.E.3. of this final rule) to permit Part D sponsors to exempt Part D drugs on either or both specialty tiers from tiering exceptions to non-specialty tiers.

Additionally, while we are sensitive to and trying to be responsive to the volatility of the specialty-tier drug market by proposing to allow Part D sponsors to have up to two specialty tiers, we remain concerned about whether our proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of two specialty tiers. As discussed in section IV.E.2 of this final rule, those stakeholders posit that permitting two specialty tiers will reduce Part D enrollee cost sharing for specialty Part D drugs. However, this would be true only for Part D drugs on the lower cost-sharing, preferred specialty tier, and only if the lower cost-sharing, preferred, specialty-tier cost sharing were set lower than 25/33 percent.

When requesting a second specialty tier, some Part D sponsors and PBMs have told us they would need to charge more than 25/33 percent for the higher cost-sharing, specialty tier. However, if we were to permit Part D sponsors to charge more than 25/33 percent for the higher cost-sharing, specialty tier, the cost sharing for drugs in the higher cost-sharing, specialty tier would likely be higher than if there were only one specialty tier. We appreciate that permitting Part D sponsors to increase cost sharing over current limits might lead to negotiations for better rebates, which could result in savings to Part D enrollees offered through, for instance, lower costs on some Part D drugs in the preferred specialty tier or lower premiums. However, in the absence of evidence to the contrary, it appears to us that if we were to permit Part D sponsors to charge higher percentages than is currently the case, Part D enrollees who need Part D drugs on the higher cost-sharing, specialty tier will pay more, and possibly significantly more, than they currently do for those drugs given that specialty tiers, by definition, consist of high-cost drugs. In other words, we remain concerned about Part D enrollee protections and do not want improved rebates on some Part D drugs to come at the expense of those Part D enrollees who could already be paying, as proposed, as much as a 33 percent coinsurance on the highest-costing

drugs. Moreover, because Part D enrollees who use high-cost Part D drugs progress quickly through the benefit, some Part D enrollees' entry into the catastrophic phase of the benefit may be advanced faster if the higher cost-sharing, specialty tier were to have a maximum allowable cost sharing that is higher than 25/33 percent. Therefore, it is unclear to us, in the aggregate, how much a second specialty tier would save the government if the second specialty tier was allowed to have a higher cost sharing than the current 25/33 percent.

In addition, while a second specialty tier might improve Part D sponsors' ability to negotiate better rebates, we also have concerns regarding discriminatory plan designs with a second, higher cost-sharing, specialty tier with cost sharing higher than the 25/33 percent that is currently permitted. If we were to allow a maximum allowable cost sharing for the higher cost-sharing, specialty tier above the 25/33 percent that is currently permitted, some Part D enrollees whose Part D drugs are placed on the higher cost-sharing, specialty tier could see their out-of-pocket (OOP) costs increase above the Defined Standard cost-sharing amount. We are concerned that the disproportionate impact on Part D enrollees who take Part D drugs on the higher cost-sharing, specialty tier runs a greater risk of discriminatory plan design. Additionally, while it is generally allowable for plans to use tier placement to steer Part D enrollees toward preferred agents, we would have to develop additional formulary checks to prevent discrimination against those Part D enrollees who require Part D drugs on the higher cost-sharing, specialty tier, and those additional formulary checks would limit the ability of plans to negotiate for tier placement between the two specialty tiers.

We proposed to set a maximum allowable cost sharing for a single specialty tier or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier as follows: (1) for plans with the full deductible provided for in the Defined Standard benefit, 25 percent coinsurance; (2) for plans with no deductible, 33 percent coinsurance; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided for in the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's

deductible from 33 percent of the initial coverage limit (ICL) under section 1860D-2(b)(3) of the Act, dividing that difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent. Shown mathematically, that is:

((ICL x 0.33) – deductible) / (ICL – deductible)

We proposed to require that a plan's second specialty tier, if any, must have a maximum allowable cost sharing that is less than the maximum allowable cost sharing of the higher cost-sharing, specialty tier. For example, if a Part D sponsor establishes a cost sharing of 25 percent on its higher cost-sharing, specialty tier, the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 25 percent. Similarly, if a Part D sponsor establishes a cost sharing of 33 percent on its higher specialty tier (permitted if the plan has no deductible, as discussed earlier in this section of this final rule), the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 33 percent. To encourage flexibility, and with the belief that we might not be able to anticipate every variation Part D sponsors might plan, we did not propose to require a minimum difference between the cost-sharing levels of the higher cost-sharing, specialty tier and a lower cost-sharing, preferred specialty tier that would apply to Part D sponsors choosing to provide two specialty tiers. As we have generally seen, for example, in relation to our policy recommending a threshold of $20 for the generic tier and "less than $20" for the preferred generic tier[58], we believe it would be unlikely that Part D sponsors would take the trouble to create two different tiers and then establish an inconsequential differential. With that, we would, of course, reexamine this policy if we find after finalizing this provision that not requiring a minimum difference between the cost-sharing levels of the two specialty tiers has created problems. Additionally, we solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier, including suggestions on requiring a minimum difference

[58] See page 212 of the Final 2020 Call Letter, available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf

between the cost-sharing levels of the two specialty tiers that can provide maximum flexibility and anticipate varied approaches that Part D sponsors might take. Lastly, nothing in our proposal would prohibit Part D sponsors from offering less than the maximum allowable cost sharing on either tier as long as the preferred specialty tier has lower cost sharing than the higher cost-sharing, specialty tier.

As mentioned in section IV.E.3 of this final rule, we have ongoing concerns that offering a lower cost-sharing, preferred specialty tier below the current 25/33 percent maximum could, in theory, lead to increased costs in lower, non-specialty tiers in order to achieve actuarial equivalence. However, because these increases in costs would be spread across the overall plan design, we believe the overall impact on Part D enrollees, would be less than the increase on individual Part D enrollee cost sharing were we to permit a maximum allowable cost sharing for the specialty tier above what is currently permitted (25/33 percent). Although we are concerned about offsetting increases to lower, non-specialty tiers, the 25/33 percent maximum allowable cost sharing is based upon the Defined Standard benefit cost sharing and therefore would provide an important Part D enrollee protection to prevent discriminatory benefit structures. Consequently, we believe this approach strikes the appropriate balance between Part D sponsor flexibility and Part D enrollee access.

In summary, we proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D sponsor may maintain up to two specialty tiers. Further, we proposed to set a maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier by adding paragraphs (d)(2)(iv)(D)(*1*), (*2*), and (*3*) which provide: (1) 25 percent coinsurance for plans with the full deductible provided under the Defined Standard benefit; (2) 33 percent coinsurance for plans with no deductible; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is between 25 and 33 percent, determined by subtracting the plan's deductible from 33 percent of the initial coverage limit

(ICL), dividing this difference by the difference between the ICL and the plan's deductible, then rounding to the nearest 1 percent.

We solicited comment on this approach. We were also interested in and solicited comments on plan benefit designs with two specialty tiers if we were to permit the higher cost-sharing, specialty tier to have a higher coinsurance than what we have proposed. Specifically, we were interested in comments that discuss whether permitting a coinsurance higher than 25/33 percent would be discriminatory.

Additionally, we note that the deductible applies to all tiers, and is not limited to, nor borne solely by, Part D enrollees taking Part D drugs on the specialty tier. Therefore, it is unclear that we should continue to differentiate the specialty tier from the other tiers on the basis of the deductible. Accordingly, we also considered adopting a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. We solicited comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible.

To summarize, we proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to: (1) specify that a Part D plan may maintain up to two specialty tiers; and (2) set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. We also proposed to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier. Additionally, we solicited comment on actuarial equivalence and the potential for discriminatory effects plan designs with two specialty tiers if we were to permit: (1) the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed; or (2) a maximum allowable cost sharing of 25 percent without regard to deductible. Finally, we also solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

We received 22 public comments concerning our proposal to set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. We received 23 public comments concerning the alternative on which we solicited comment to permit the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed. We received 10 public comments concerning the alternative on which we solicited comment to permit a maximum allowable cost sharing of 25 percent without regard to deductible. We received 18 public comments concerning our proposal to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier; and 18 public comments concerning the alternative on which we solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Most commenters supported CMS's proposals to set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. A commenter asserted that under current policy, coinsurance for specialty tiers can be as high as 50 percent.

Response: We thank the commenters for their support. We are not clear on the commenters' assertion that coinsurance for the specialty tiers can be as high as 50 percent; it has been our longstanding policy – which we are codifying in this rule – that Part D sponsors may not charge more than 25/33 percent coinsurance, depending on the plan's deductible. We thank the commenter, and if the commenter has evidence to the contrary, we welcome further input on this matter.

Comment: Some commenters opposed CMS's proposal and supported the alternative on which CMS solicited comment to permit the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing CMS proposed. Some commenters suggested that CMS should keep the existing maximum allowable cost sharing for the lower cost-sharing, preferred specialty tier at 25/33 percent and establish the maximum allowable cost sharing for the higher cost-sharing, specialty tier with a range between 30 and 40 percent, inclusive, depending on the deductible. Other commenters suggested something of a hybrid approach between our proposal and the previous approach in which CMS would permit Part D sponsors to set the cost sharing for (1) the lower cost-sharing, preferred specialty tier *at any amount lower* than that of the other specialty tier *and* (2) the higher cost-sharing, specialty tier higher than the 25/33 percent maximum allowable cost sharing *as long as* the cost sharing between the two tiers averages, or is actuarially equivalent to, 25/33 percent. These latter commenters further suggested that CMS could set a maximum allowable cost sharing for the higher cost-sharing, specialty tier at 50 percent; however, they did not specify whether this 50 percent would be applied with regard to the deductible.

Response: We are not persuaded by commenters recommending that we permit Part D sponsors offering two specialty tiers to have coinsurance for the higher-cost sharing specialty tier that exceeds the 25/33 percent maximum we proposed. We continue to have significant concerns that allowing specialty-tier cost sharing to exceed 25/33 percent, especially when an enrollee may not be able to receive a tiering exception, could result in discriminatory plan designs, particularly for enrollees who take high-cost drugs that meet the specialty-tier cost threshold we are finalizing in this final rule. We remain concerned that, given the high cost of drugs that meet such specialty-tier cost threshold, increased cost-sharing could leave more Part D enrollees unable to afford what could be life-saving drugs. Moreover, as noted in section IV.E.2 of this final rule, our specialty-tier cost sharing maximum has historically been based on the Defined Standard benefit as a Part D enrollee protection, and the maximum allowable cost

sharing of 25/33 percent that we proposed is dependent upon the plan's deductible. Commenters recommending higher cost sharing for the higher cost-sharing specialty tier offered no analysis or approach that would allow us to determine how the higher cost-sharing level would align with the Defined Standard benefit. For this reason, we similarly believe it is inappropriate to finalize a hybrid approach as some commenters suggested, as we would need more information and analysis before we could determine how such a hybrid approach would be structured. We can consider such a policy for future rulemaking, if warranted. We welcome further input from stakeholders, and we thank the commenters.

Comment: Most commenters preferred that the maximum allowable cost sharing for the specialty tiers continue to be expressed as a range, with a specific value for each plan that is dependent upon the plan's deductible. However, some commenters supported the alternative on which CMS solicited comment to permit a maximum allowable cost sharing of 25 percent without regard to deductible. A commenter agreed with this, in principle, but suggested that CMS should permit a maximum allowable cost sharing of 33 percent without regard to the deductible, and, some commenters suggested that plans should be permitted to establish the cost sharing for the specialty tier(s) at coinsurance greater than 25 percent if there is no deductible.

Response: Although we also solicited comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible, we did not receive any examples of this. We thank the commenters who expressed support or opposition to this alternative, but we were not persuaded to adopt a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. None of the comments persuaded us that the current policy, which we proposed to codify and are now adopting, is insufficient.

We note that under the current and proposed policies, Part D plans are permitted to establish the cost sharing for the specialty tier greater than 25 percent, up to and including 33 percent, if there is no deductible. As detailed earlier in this section of this final rule, we are

concerned that, unlike our current maximum allowable cost sharing of 25/33 percent, establishing a maximum allowable cost sharing of 33 percent without regard to the deductible could be discriminatory.

Comment: Some commenters suggested that CMS should contemplate other changes to the non-preferred brand/drug tiers to address high Part D enrollee cost sharing. For example, some commenters suggested that a preliminary analysis indicates that, for plan benefit designs with coinsurance for the non-preferred brand/drug tiers, 75 percent of Part D enrollees receiving drugs on this tier pay more than, and some significantly more than, the corresponding amount for such tier when the plan uses copayments (for example, $100 for contract year 2021). These commenters suggested that CMS should monitor this, particularly if enacting any changes to the specialty tiers.

Response: We thank the commenters for their comments, and welcome additional detail on this to consider it for future rulemaking.

Comment: Some commenters supported CMS's proposal to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier, encouraging CMS to allow plans to innovate in this area. However, other commenters preferred the alternative on which CMS solicited comment to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier. Some commenters suggested that CMS establish a difference of 5 or 8 percent in cost sharing between the two specialty tiers; some commenters suggested that CMS establish the maximum allowable cost sharing for the lower cost-sharing, specialty tier at 15, 17, or 20 percent while maintaining the maximum allowable cost sharing of 25/33 percent for the higher cost-sharing, specialty tier. Some commenters encouraged CMS to give Part D sponsors the option set the cost sharing for their specialty tier(s) lower than the maximum allowable cost sharing CMS has specified.

Finally, a commenter suggested that CMS should provide by regulation that CMS will annually specify a minimum percentage differential that CMS determines will be likely to

substantially incent utilization of the products on the preferred specialty tier over utilization of the products on the higher cost-sharing, specialty tier, and that minimum differential would be subtracted from the coinsurance for the plan's higher cost-sharing, specialty tier (in other words, between 25 and 33 percent, inclusive, depending on the plan's deductible) to result in the maximum allowable cost sharing for the lower cost-sharing, preferred specialty tier.

Response: While we appreciate the specific suggestions provided by commenters, we decline to adopt these suggestions. None of the commenters suggesting specific differentials provided any analysis to support those thresholds or reasonable extrapolation from the Defined Standard benefit (for example, the 25/33 percent).

Finally, while we are intrigued by the commenters' suggestion that we specify a minimum percentage differential that we determine will be likely to substantially incent utilization of the products on the preferred specialty tier versus those on the higher cost-sharing, specialty tier, we decline to adopt this approach. Because a Part D sponsor's decision to place a Part D drug on one tier versus another is multifactorial, it is unclear how we could determine a percentage that is "likely to substantially incent utilization" of the products on the preferred specialty tier versus those on the higher cost-sharing, specialty tier. However, we welcome additional information on this suggestion, and we thank the commenter.

After considering the comments, we are finalizing without modification our proposals to: (1) add new paragraphs § 423.104(d)(2)(iv)(D)(*1*) through (*3*) to establish a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, for plans with two specialty tiers, the higher cost-sharing, specialty tier and (2) permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the other specialty tier.

5. Two Specialty Tiers and Tier Composition

A few commenters on the Draft 2020 Call Letter suggested that we should create a lower cost specialty tier for generic drugs and biosimilar biological products, and that such a tier should be limited to only such products. We declined to propose such a policy for this rule. First, we

wish to provide maximum flexibility to Part D sponsors that might find, for instance, that a brand-name Part D drug costs less with a rebate than a generic equivalent or corresponding biosimilar biological product. Moreover, generic drugs and biosimilar biological products that meet the specialty-tier cost threshold may not always be the lowest-priced product. Second, nothing in our proposal would prohibit Part D sponsors from setting up such parameters should they choose (provided they meet all other requirements, including the proposed maximum allowable cost sharing). Therefore, in order to provide more flexibility for plans to generate potential savings through benefit design and manufacturer negotiations, we did not propose to prescribe which Part D drugs may go on either specialty tier. However, such placement will be subject to the requirements of our formulary review and approval process under § 423.120(b)(2). Additionally, consistent with our current policy, we will continue to evaluate formulary change requests involving biosimilar biological products on the specialty tiers on a case-by-case basis to ensure they continue to meet the requirements of our formulary review and approval process. (See § 423.120(b)(5).)

We solicited comment on whether Part D sponsors should restrict the lower cost-sharing, preferred specialty tier to only generic drugs and biosimilar biological products while also placing them along with any other Part D drugs meeting the specialty-tier cost threshold on the higher cost-sharing, specialty tier. In other words, either brand or generic drugs and biosimilar biological products would be placed on the higher cost-sharing, specialty tier, but only generic drugs and biosimilar biological products would be placed on the preferred specialty tier. We stated that we were particularly interested in comments that discuss what impact such a policy would have on non-specialty tiers.

We received 30 public comments concerning our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2) ; and 30 public comments concerning the alternative on which we

solicited comment to require Part D sponsors to restrict the preferred specialty tier to only generic drugs and biosimilar biological products, while permitting Part D sponsors to have generic drugs, biosimilar biological products, and reference/originator drugs and biological products on the higher cost-sharing, specialty tier.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, think tanks, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Most commenters supported CMS's proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds CMS proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2) and opposed the alternative on which CMS solicited comment to require Part D sponsors to restrict the preferred specialty tier to only generic drugs and biosimilar biological products, while permitting Part D sponsors to have generic drugs, biosimilar biological products, and reference / originator drugs and biological products on the higher cost-sharing, specialty tier.

Response: We thank the commenters for their support.

Comment: Several commenters opposed CMS's proposal. Some commenters asserted that CMS should require Part D sponsors to use their second specialty tier to encourage greater use of less-expensive biosimilar biological products and greater price competition for specialty-tier drugs, but did not provide suggestions on how to do so. Some commenters suggested that current formulary and tiering practices discourage utilization of generic specialty-tier drugs. Some commenters asserted that CMS should only allow brand products on the higher cost-sharing, specialty tier, and some commenters asserted that generic drugs and biosimilar biological products should be exempt from specialty tier placement altogether. Some commenters suggested permitting generic drugs and biosimilar biological products on the higher

cost-sharing, non-specialty tier and/or the same tier as brand specialty-tier drugs and biological products would discourage the use of generic drugs and biosimilar biological products and hamper the research and development pipeline of such products. Conversely, some commenters asserted that current market incentives for generic drugs and biosimilar biological products are sufficient.

Response: We continue to strive to encourage the use of generic drugs and biosimilar biological products. However, we believe that our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2) is appropriate because restricting which types of products may be included on a particular specialty tier may result in fewer generic and biosimilar products being included on the formulary. Part D plans can frequently negotiate lower net prices for brand drugs than generic drugs and biosimilar biological products, and if we were to require preferred placement of a product that has the potential to be more expensive, Part D sponsors may elect not to include the generic drug or biosimilar biological product on their formulary at all. (We note that there currently are no interchangeable biological products on the market.)

Comment: Some commenters asserted that tier placement should have a clinical basis. Additionally, some commenters asked CMS to ensure that utilization management and prior authorization are not inappropriately imposed to prefer brand products over generic drugs and biosimilar biological products.

Response: We detailed the components of our annual formulary review and approval process in our May 2019 final rule (84 FR 23835). As part of this review and approval process, we perform multiple reviews related to the clinical appropriateness of both tier composition and utilization management strategies. For additional information, please also see section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at https://www.cms.gov/

Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

Comment: Some commenters, in expressing their opposition to CMS's proposal to permit Part D sponsors to maintain up to two specialty tiers: (1) agreed with CMS's assertion that the currently available tier-model structures (which already allow Part D sponsors to negotiate rebates and distinguish their preferred, high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier) could potentially drive the same rebates as two specialty tiers; (2) suggested that Part D sponsors could place preferred, high-cost Part D drugs on the specialty tier and place less preferred agents on the non-preferred brand/drug tiers; and (3) suggested that, before implementing further changes to the specialty tiers, CMS needs to provide more detail on why the use of either of the aforementioned options (that is, (1) placing preferred, high-cost Part D drugs on the preferred brand tier while placing less preferred agents on the specialty tier, or, (2) placing preferred, high-cost Part D drugs on the specialty tier while placing less preferred agents on the non-preferred brand/drug tiers) is insufficient to achieve our stated policy goals for permitting Part D sponsors to maintain up two specialty tiers.

Response: While these options certainly are available, we do not foresee harm in finalizing our proposal to permit Part D sponsors to maintain up to two specialty tiers under the parameters we have established in this final rule while monitoring the uptake and outcomes associated with the use of a second specialty tier as Part D sponsors implement it. Conversely, as specialty-tier drugs play an increasingly important role in the prescription drug marketplace, limiting Part D sponsors to either of the aforementioned options could adversely impact the Medicare Part D marketplace. Currently, only 8 percent of Part D plans offer preferred brand tiers with coinsurance.

Limiting Part D sponsors to the option of placing preferred specialty-tier drugs on the preferred brand tier could lead to more plans adopting coinsurance for the preferred brand tier,

which could significantly decrease competition among plans in the Part D marketplace as plan benefit designs become less varied and more like the Defined Standard benefit. Conversely, if Part D sponsors were limited to placing non-preferred, specialty-tier eligible drugs on the non-preferred brand/drug tiers, Part D enrollees whose specialty-tier eligible drugs are on this tier could face cost sharing of up to 50 percent coinsurance, which, given the high cost of specialty-tier eligible drugs, is substantially more than they would pay if the drug were on a specialty tier, with the maximum allowable cost sharing of 25/33 percent that we are finalizing in this final rule.

Comment: Some commenters believed that CMS's combined proposals (which would (1) permit Part D sponsors to maintain up to two specialty tiers and (2) give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds CMS proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2)) are inextricably linked to problems concerning the role rebates play within Part D and, due to the high cost of specialty-tier drugs, will exacerbate the effect these problems have on costs incurred by Part D enrollees and the government.

Response: Because we are setting a maximum cost sharing for the higher cost-sharing, specialty tier at 25/33 percent, we do not believe that any Part D enrollee or the government will be worse off than today. Nonetheless, we intend to monitor the uptake of and outcomes associated with the use of a second specialty tier. Finally, we decline to adopt the recommendation that we require the preferred tier to reflect clinically appropriate therapeutic alternatives with the lower list price. Section 1860D-11(i) of the Act, otherwise known as the non-interference clause, prohibits us from (1) interfering with the negotiations between drug manufacturers and pharmacies and Part D sponsors, and (2) requiring a particular formulary or instituting a price structure for the reimbursement of covered Part D drugs. For additional information regarding noninterference, please see our rule titled, "Medicare Program; Contract

Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29843) at 79 FR 29844, and 79 FR 29874-5.

Comment: Some commenters asserted that transitioning between biosimilar biological products, reference biological products, or both can jeopardize patient safety due to immunogenicity.

Response: We would refer commenters to the FDA regarding the safety and efficacy of biological products, including biosimilar biological products.

After considering the comments, we are finalizing without modification our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the cost threshold we are finalizing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2).

6. Establishing and Increasing the Specialty-Tier Cost Threshold

To effectuate the specialty tier, it was necessary to determine which Part D drugs could be placed on a specialty tier. Consequently, we developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier. We have sought comment on both this methodology used to establish the specialty-tier cost threshold and the resultant value of the specialty-tier cost threshold when publishing the annual Draft Call Letter. Most recently, commenters on the Draft 2020 Call Letter were largely supportive of having a methodology in place to annually evaluate and adjust the specialty-tier cost threshold, as appropriate. While some commenters wanted to maintain the current level (and others wanted to eliminate the specialty tier or reduce its cost sharing), there was broad support to regularly increase the specialty-tier cost threshold. Some comments requested annual increases, while others wanted us to tie increases to the specialty-tier cost threshold to drug inflation, or benefit parameters. As we detail later in this discussion, we proposed to codify, with some modifications, the same outlier PDE analysis we have historically used. Our proposed annual methodology would account for rising drug costs, as well as any

potential changes in utilization. By identifying the top 1 percent of 30-day equivalent PDEs, our proposal aims to create a specialty-tier cost threshold that is representative of outlier claims for the highest-cost drugs. By using PDEs, the proposed analysis would also reflect the fact that the numbers of Part D enrollees filling prescriptions for high-cost drugs as a percentage of all drug claims may vary from year to year. Given the general support for regular increases in the specialty-tier cost threshold, we proposed to make adjustments to the specialty-tier cost threshold based on a specific methodology, as discussed later in this section.

Beginning in 2007, we established the specialty-tier cost threshold at $500 per month[59] based on identifying outlier claims (that is, the top 1 percent of claims having the highest negotiated prices as reported on the PDE, adjusted, as described in this section of this final rule, for 30-day equivalent supplies) and increased the threshold to $600 beginning in contract year 2008. The specialty-tier cost threshold remained at $600 per month from contract years 2008 through 2016.[60,61] In the 2016 analysis for contract year 2017 (using contract year 2015 PDE data), the number of claims for 30 day-equivalent supplies with negotiated prices meeting the existing $600 per-month cost threshold exceeded 1 percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment (in 2008), supported an increase in the specialty-tier cost threshold for contract year 2017. To adjust the specialty-tier cost threshold, we applied the annual percentage increase used in the Part D benefit parameter updates (that is, 11.75 percent for contract year 2017) to the $600 threshold. This increase in the specialty-tier cost threshold (that is, $70.50), rounded to the nearest $10 increment (that is, $70), was sufficient to reestablish the 1 percent outlier threshold for PDEs having negotiated prices for 30-day equivalent supplies greater than the threshold. Since contract year 2017, the specialty-tier cost threshold has been $670 per month.

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[59] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/CY07FormularyGuidance.pdf

[60] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf

[61] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

In our April 2018 final rule, we defined specialty tier in regulation at § 423.560 to mean a formulary cost-sharing tier dedicated to very high-cost Part D drugs and biological products that exceed a cost threshold established by the Secretary (83 FR 16509). To improve transparency, we proposed to codify current methodologies for calculations relative to the specialty tier, with some changes. As noted in sections IV.E.3 and IV.E.4. of this final rule, it was necessary to establish the composition of a specialty tier in order to effectuate specialty tier exceptions and anti-discrimination policies. Under § 423.560, only very high-cost drugs and biological products that meet or exceed a cost threshold established by the Secretary may be placed on a plan's specialty tier (for example, a negotiated price of or exceeding $670 per month for coverage year 2020). Current guidance at section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual describes these high-cost drugs and biological products as those having Part D sponsor-negotiated prices that exceed a dollar-per-month amount we established in the annual Call Letter, which has noted the historical use of a threshold under which approximately 99 percent of monthly PDEs adjusted for 30-day equivalent supplies have been below the specialty-tier cost threshold.

In setting the specialty-tier cost threshold, we have historically analyzed PDE data for the plan year that ended 12 months before the applicable plan year (for example, we used contract year 2017 PDE data to determine the cost threshold for contract year 2019). First, we have calculated the number of 30-day equivalent supplies reported on each PDE. We have considered a 30-day equivalent supply to be any days' supply, as reported on each PDE, of less than or equal to 34 days. Thus, a PDE with a 34-days' supply has been considered one 30-day equivalent supply. (This reflects the fact that a full supply of medication for a Part D enrollee could equal less than a month's supply, or reflect manufacturer packaging. For instance, we did not want to triple the cost of a 10-day course of antibiotics to determine the 30-day equivalent supply because that would overstate the Part D enrollee's cost for the full prescription). If the days' supply on the PDE is greater than 34, the 30-day equivalent supply is equal to the PDE's days'

supply divided by 30. Thus, for example, a PDE with a 90-day supply has been considered as three 30-day equivalent supplies. Similarly, a PDE with a drug that has been dispensed in a package containing a 45-days' supply has been considered as 1.5 30-day equivalent supplies. This includes long-acting drugs, including, but not limited to long-acting injections. For example, a single injection that is considered to be a 90-days' supply has been considered as three 30-day equivalent supplies.

After determining the number of 30-day equivalent supplies for each PDE, we have calculated the 30-day equivalent negotiated price for the PDE by dividing the PDE's negotiated price by the number of 30-day equivalent supplies reflected on the PDE. Thus, for example, if the PDE is for a 90-days' supply and has a negotiated price of $810, that PDE contains three 30-day equivalent supplies, and the 30-day equivalent negotiated price is $270.

Next, taking into consideration the 30-day equivalent negotiated prices for all Part D drugs for which PDE data are available, we have identified the PDEs with 30-day equivalent negotiated prices that reflect the top 1 percent of 30 day-equivalent negotiated prices, and have maintained the specialty-tier cost threshold at an amount that corresponds to the lowest 30-day equivalent negotiated price that is within the top 1 percent of all 30-day equivalent negotiated prices.

We note that this process may result in dose specificity of eligibility for placement on the specialty tier, such that one strength of a Part D drug may be eligible but another strength may not. For example, suppose that Part D drug X is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. The 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold, are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

We believe our existing policy to set the specialty-tier cost threshold such that only the top 1 percent of 30-day equivalent negotiated prices would exceed it is consistent with the purpose of the specialty tier – that is, that only the highest-cost Part D drugs are eligible for placement on the specialty tier. For this reason, we proposed to codify a similar process to adjust and rank PDE data as the basis for determining the specialty-tier cost threshold, as described in this section of this final rule. Specifically, instead of 30-day equivalent negotiated prices, we proposed to determine the 30-day equivalent ingredient cost to set the specialty tier-cost threshold in the same manner as we have historically done, as described previously in this section.

In addition, to maintain stability in the specialty-tier cost threshold, we proposed to set the specialty-tier cost threshold for contract year 2021 to reflect the top 1 percent of 30-day equivalent ingredient costs, at an amount that corresponds to the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs. We also proposed to undertake an analysis of 30-day equivalent ingredient costs annually, and to increase the specialty-tier cost threshold for a plan year only if we determine that no less than a ten percent increase in the specialty-tier cost threshold, before rounding to the nearest $10 increment, is needed to reestablish the specialty-tier cost threshold that reflects the top 1 percent of 30-day equivalent ingredient costs.

As a hypothetical example, suppose that, in 2020, when analyzing contract year 2019 PDE data for contract year 2021, we find that more than 1 percent of PDEs have 30-day equivalent ingredient costs that exceed the contract year 2020 specialty-tier cost threshold of $670. Further, suppose that we find that 1 percent of the PDEs have 30-day equivalent ingredient costs that exceed $685. This $15 difference represents a 2.24 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, we would not increase the specialty-tier cost threshold for contract year 2021.

However, if we suppose that, instead of $685, we find that 1 percent of the PDEs have 30-day equivalent ingredient costs that exceed $753, then in this scenario, the $83 change represents a 12.39 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, because this would be a change of more than 10 percent, we would set the specialty-tier cost threshold for contract year 2021 at $750 which is the nearest $10 increment to $753.

We solicited comment on this proposal. Because rounding down, as in the previous example, would technically cause the new specialty-tier cost threshold to account for very slightly more than 1 percent of 30 day-equivalent ingredient costs, we also considered the alternative that we would always round up to the next $10 increment. Using the previous example, we would have set the threshold for contract year 2021 at $760 instead of $750. This alternative would: (a) better ensure that the new specialty-tier cost threshold actually reflects the top 1 percent of claims adjusted for 30-day equivalent supplies, and (b) provide more stability to the specialty-tier cost threshold, that is to say, it will theoretically not need to be changed as frequently, because rounding down will always result in a specialty-tier cost threshold that would include more than the top 1 percent of 30-day equivalent ingredient costs. We do not expect that this alternative would significantly impact the number of Part D drugs that would meet our proposed specialty-tier cost threshold. We solicited comment on this alternative approach to rounding and stated that we could finalize an amended version of our proposed language at § 423.104(d)(2)(B) to reflect such alternative. We proposed to annually determine whether the adjustment would be triggered using the proposed methodology, and if it is, we would apply the proposed methodology to determine the new specialty-tier cost threshold, which we would announce via an HPMS memorandum or a comparable guidance document. Finally, we proposed for contract year 2021 that we would apply our proposed methodology to the contract year 2020 specialty-tier cost threshold of $670, and if a change to the methodology based on

comments received on this final rule would result in a change to that threshold, we stated that we will announce the new specialty-tier cost threshold in this final rule.

We have concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point of sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. Consequently, as noted previously, we proposed to use the ingredient costs associated with 30-day equivalent supplies when we determine the specialty-tier cost threshold according to the methodology proposed earlier in this preamble. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price; however, this change to use the ingredient cost ensures that we are using the most predictable of all the components of the negotiated price upon which to base the specialty-tier cost threshold.

Using the methodology in this final rule and contract year 2019 PDE data that we have to date, the specialty-tier cost threshold for contract year 2021 would be $780 as a 30-day equivalent ingredient cost. To determine this threshold, we analyzed 2.2 billion PDEs, and determined the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs to be $780, which did not require rounding. Therefore, we would increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for

contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). While this change will impact the specific dollar-threshold amount for specialty-tier eligibility, the specialty-tier cost threshold still accounts for the top 1 percent of all claims, as adjusted for 30-day equivalent supplies. Due to the increased costs of prescription drugs since the previous $670 specialty-tier cost threshold was set several years ago, the top 1 percent of all claims, as adjusted for 30-day equivalent supplies, cost more, on average. Moreover, we estimate that the change from using negotiated price to using ingredient cost only will result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have if we continued to use the 30-day equivalent negotiated price.

Additionally, consistent with current guidance in section 30.2.4 in Chapter 6 of the Medicare Prescription Drug Benefit Manual, we consider claims history in reviewing the placement of Part D drugs on Part D sponsors' specialty tiers. Consequently, we proposed to codify current guidance that a Part D drug will be eligible for placement on a specialty tier if the majority of a Part D sponsor's claims for that Part D drug, when adjusted for 30-day equivalent supplies, exceed the specialty-tier cost threshold. However, for Part D drugs newly approved by the FDA for which Part D sponsors would have little or no claims data because such drugs have only recently become available on the market, we proposed to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of their negotiated prices based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths. If, based on their estimated 30-day equivalent ingredient cost, the newly FDA-approved Part D drug is anticipated to exceed the specialty-tier cost threshold most of the time (that is, more than 50 percent of the time), we would allow Part D sponsors to place such drug on a specialty tier. Finally, such placement would be subject to our review and approval as part of our annual formulary review and approval process.

We proposed to add paragraphs (d)(2)(iv)(A), (B), and (C) to § 423.104 and to cross reference this section in our revised definition of specialty tiers, which we proposed to move to § 423.104, as described later in this section. Specifically, we proposed in paragraph (d)(2)(iv)(A) to described in paragraphs (d)(2)(iv)(A)(*1*) through (*4*) the manner by which we set the specialty-tier cost threshold, and further, to describe in paragraph (d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier. In paragraph (d)(2)(iv)(A)(*1*) we proposed to specify that we use PDE data, and further, use the ingredient cost reflected on the PDE to determine the ingredient costs in dollars for 30-day equivalent supplies of drugs. In paragraph (d)(2)(iv)(A)(*2*) we proposed to specify how we determine 30-day equivalent supplies from PDE data, such that if the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one, and if the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on the PDE divided by 30. We proposed that paragraph (d)(2)(iv)(A)(*3*) would specify that we then determine the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data. We proposed that paragraph (d)(2)(iv)(A)(*4*) would specify that, except as provided in paragraph (B), the amount determined in paragraph (d)(2)(iv)(A)(*3*) is the specialty-tier cost threshold for the plan year. Further, we proposed that paragraph (d)(2)(iv)(A)(*5*) would specify that, except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, we will approve the placement of a Part D drug on a specialty tiers when that Part D sponsor's claims data from the plan year that ended 12 months prior to the applicable plan year demonstrate that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies that exceed the specialty-tier cost threshold.

We proposed in paragraph (d)(2)(iv)(B) to describe the methodology we will use to increase the specialty-tier cost threshold. Specifically, we proposed to increase the specialty-tier

cost threshold for a plan year only if the amount determined by paragraph (d)(2)(iv)(A)(*3*) for a plan year is at least ten percent above the specialty-tier cost threshold for the prior plan year. We proposed that if an increase is made, we would round the amount determined in proposed paragraph (d)(2)(iv)(A)(*3*) to the nearest $10. That amount would be the specialty-tier cost threshold for the applicable plan year.

Finally, we proposed paragraph (d)(2)(iv)(C) to specify that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

As mentioned in this section of this final rule, to align the definition of specialty tier with our proposal to allow Part D sponsors to have up to two specialty tiers, we first proposed to move the definition of specialty tier from § 423.560 to appear in § 423.104(d)(2)(iv) as part of a proposed new section on specialty tiers that also includes the methodology for determining the specialty-tier cost thresholds and maximum allowable cost sharing. (We also proposed to revise § 423.560 and § 423.578(a)(6)(iii) to cross reference the placement of that definition in § 423.104(d)(2)(iv).) Additionally, we proposed to amend the definition of specialty tier to reflect our proposal to allow Part D sponsors to have up to two specialty tiers. With respect to the phrase "and biological products," for the reasons discussed in the section IV.E.3 of this final rule, (specifically, that biological products are already are included in the definition of a Part D drug at § 423.100), we also proposed a technical change to the definition of specialty tier to remove the phrase "and biological products." Therefore, we proposed to define specialty tier at § 423.104(d)(2)(iv) to mean a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in **§** 423.104(d)(2)(iv)(A)(*2*)) that are greater than the specialty-tier cost threshold specified in **§** 423.104(d)(2)(iv)(A).

To summarize, we proposed to: (1) amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); (3) add new paragraph (d)(2)(iv)(A) which

describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty tier; (4) add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold; and (5) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We solicited comment on specifying at the new § 423.104(d)(2)(iv)(B) that we would round up to the nearest $10 increment.

We received 8 public comments concerning our proposal to amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); and 8 public comments concerning our proposal to amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv). We received 10 public comments concerning our proposal to add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty tier. We received 12 public comments concerning our proposal to add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold; and 6 public comments concerning our proposal to add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We received 7 public comments concerning our proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*).

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers,

pharmacists and pharmacies, wholesale distributors, think tanks, and non-partisan Congressional agencies.

A summary of the comments on amending, moving, and cross-referencing the definition of specialty tier and data used to determine the specialty-tier cost threshold and our responses follow.

Comment: Most commenters supported CMS's proposals. We did not receive any comments on the alternative on which we solicited comment to specify at the new § 423.104(d)(2)(iv)(B) that we would round up to the nearest $10 increment. We received unanimous support of our proposals to (1) amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); and (3) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

Response: We thank the commenters for their support. We will not finalize the alternative on which we solicited comment to specify that we would round up to the nearest $10 increment at this time, but may consider it for future rulemaking. We will finalize without modification our proposal to add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. This provision will apply for coverage year 2022. We therefore are not finalizing our proposal to specify a specialty-tier cost threshold of $780 for 2021.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as

discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase "and biological products." Additionally, paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

A summary of the comments on the methodology to determine the specialty-tier cost threshold and a Part D drug's eligibility for placement on the specialty tier and our responses follow.

Comment: Some commenters supported CMS's methodology to establish the specialty-tier cost threshold, but were opposed to the maximum dose being used to determine the specialty-tier eligibility for newly-FDA-approved drugs. Some commenters believed that: (1) the maximum dose should not be used to evaluate newly-approved drugs for specialty-tier eligibility; (2) for newly-FDA approved drugs, CMS should require Part D plans to estimate the 30-day equivalent ingredient cost for each drug product strength, package size, and formulation level, similar to how it is already done for already FDA-approved Part D drugs; and (3) CMS should also codify language at § 423.104 regarding dose specificity and dose optimization for all drugs.

Response: We thank the commenters for their perspective on the process for newly FDA-approved drugs. We agree that we need to provide more detail on what we meant in our preamble when we stated that we proposed to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of newly-FDA-approved drugs "based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths."

We did not mean to suggest that only maximum doses would qualify for the specialty tier. Rather, we would expect Part D sponsors to estimate the 30-day equivalent ingredient cost of a drug, taking into account dose optimization – which, based on the maximum FDA-approved dose of a medication, consolidates the Part D enrollee's dose into the fewest number of dose units (for example, tablets) – and dose specificity – which is based on the price applied to the particular strength and dosage form of the drug.

To illustrate that the process for determining a Part D drug's specialty-tier eligibility should take into account dose optimization and dose specificity for both already-FDA approved drugs (for which Part D sponsors would have claims history) and newly-FDA approved drugs (for which Part D sponsors would have little to no claims history), we clarify the example earlier in this section (section IV.E.6) of this final rule. We gave the example of "Part D drug X" that is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. Regarding dose specificity, the 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold, are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

Regarding dose optimization, using the previous example, suppose "Part D drug X" is administered once daily, and the maximum dose is 30mg once daily. Suppose a Part D enrollee takes the maximum dose of 30mg once daily. The Part D enrollee could accomplish that by taking three 10mg tablets, one and a half 20mg tablets, or one 30mg tablet. However, because the 30mg tablets yield the fewest number of dose units for the Part D enrollee to achieve the required dose, dispensing 30, 30mg tablets for a 30-day supply is indicated to be "dose optimized" relative to the other options. Although prescriptions for 30 30mg tablets or 90 10mg tablets each cost $900, because the prescription for 90 10mg tablets is not dose optimized, it (still) does not qualify for the specialty-tier cost threshold.

Because our proposed language at (d)(2)(iv)(A)(*6*) applied to Part D drugs except those newly-approved by the FDA, in response to the comments, we wish to clarify the process for newly-FDA approved drugs. Therefore, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drug such that we will approve placement of a newly-FDA-approved Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated price for a 30-day equivalent supply is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to our review and approval as part of our annual formulary review and approval process.

While we appreciate the commenters' suggestion that we codify language at § 423.104 concerning dose specificity and dose optimization, we do not believe that we could effectively do so, given the myriad drugs, conditions, different doses for such conditions, dosage forms, package sizes, etc., that factor into these determinations, which can sometimes be quite complicated. We do not want to inadvertently exclude nuanced, but clinically relevant dose optimization strategies. Consequently, we will consider potential language for future notice and comment rulemaking.

Comment: Some commenters suggested that moving from negotiated price to ingredient cost may increase the number of drugs eligible for the specialty tier since negotiated prices may be lower than average wholesale price (AWP) and that CMS should ensure that the switch from negotiated price to ingredient cost tracks the medications captured by the current threshold. Some commenters suggested that if CMS finalizes this provision with 30-day equivalent negotiated price (instead of 30-day equivalent ingredient cost), CMS needs to clarify which definition of negotiated price.

Response: We estimate that the change from using negotiated price to using ingredient cost only would result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have met the threshold if we continued to use the 30-

day equivalent negotiated price. In other words, in our preliminary analysis, moving from negotiated price to ingredient cost decreased the number of drugs eligible for the specialty tier. However, we will continue to monitor the uptake and outcomes associated with these proposals. We are finalizing the provision to establish a Part D drug's eligibility for placement on the specialty tier using the ingredient cost.

Comment: Some commenters requested clarity on why CMS is codifying the existing methodology while at the same time proposing a substantive change, and inquired why CMS does not simply propose the change. The commenters added that in proposing to move away from the negotiated price and use the ingredient cost that CMS has, in essence, removed the dispensing fee from the determination of a Part D drug's eligibility for specialty-tier placement, but that CMS has not specified if there is a specific issue with dispensing fees that would warrant removing them altogether from the calculation of the specialty tier cost threshold. These commenters then inquired if CMS had another definition for ingredient cost, and suggested that if so, CMS needs to spell this out.

Response: We proposed to codify our longstanding policy with certain changes to improve the transparency and consistency of the specialty tier cost threshold.

We have concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point of sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of

negotiated price upon which to base the determination of the specialty-tier cost threshold. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price.

Use of the ingredient cost in lieu of the negotiated price for purposes of determining the specialty-tier cost threshold does not remove the dispensing fee from the negotiated price. Rather, as previously noted, we are merely using the most stable portion of the negotiated price to determine the specialty tier cost threshold. Finally, by ingredient cost, we mean the ingredient cost that is reported on the PDE.

We are finalizing our proposal describing the methodology by which we set the specialty-tier cost threshold, and a Part D drug's eligibility for placement on the specialty tier with one modification. In response to comments, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

A summary of the comments on the methodology to increase the specialty-tier cost threshold and our responses follow.

Comment: Most commenters supported CMS's proposal describing the methodology CMS will use to increase the specialty-tier cost threshold.

Response: We thank the commenters for their support.

Comment: Some commenters opposed CMS's proposed 10 percent threshold for change for updating the specialty-tier cost threshold, and suggested that drugs that no longer meet the threshold should be removed from the specialty tier, regardless of the magnitude of the threshold's change. Some commenters were concerned about products not meeting the specialty-tier cost threshold from one year to the next, and consequently moving in and out of the specialty tier from one year to the next, which could cause Part D enrollee confusion. Some commenters noted a tension between tiering exceptions, use of the ingredient cost in lieu of the

negotiated price for purposes of determining the specialty-tier cost threshold, and increases to the specialty-tier cost threshold, noting that, as drugs no longer qualify for the specialty tier and are moved to a non-specialty, non-preferred brand/drug tier, Part D enrollees could potentially pay more for a preferred specialty tier drug than a non-specialty, non-preferred drug, even though the non-specialty, non-preferred drug is the less expensive product. Additionally, some commenters suggested that CMS should clarify how our proposal to revise the specialty-tier cost threshold could impact the distribution of generic drugs and biosimilar biological products that are able to be placed on the specialty tier. Finally, some commenters suggested that CMS should address sudden increases, perhaps due to a sudden increase in the utilization of specialty-tier drugs.

Response: We agree that the specialty tier should consist of only the highest-cost drugs. However, as the commenters noted, to decrease Part D enrollee confusion arising from year-to-year changes in the specialty-tier cost threshold, we must balance the limitation of the specialty tier to the highest-drugs with the need for stability in the specialty-tier cost threshold. Nonetheless, we wish to clarify that, even absent any increase in the specialty-tier cost threshold, if the price of a drug changes, and it no longer meets the specialty-tier cost threshold, it must be removed from the specialty tier at the beginning of the next plan year.

While we acknowledge the commenters' concerns about the tension between tiering exceptions, the specialty-tier cost threshold, tier composition (that is, as Part D drugs no longer meet the specialty-tier cost threshold and are potentially placed on other, non-specialty tiers), and Part D enrollee cost sharing, this dynamic exists today and our policy would not change this. We also note that if Part D drugs, including generic drugs and biosimilar biological products, were no longer eligible for specialty-tier placement and subsequently placed on a non-specialty, non-preferred tier in the following plan year, an enrollee could then request a tiering exception for that drug.

We also appreciate that the commenters' suggestion of sudden increases comes at a time of unprecedented uncertainty regarding the specialty tiers in light of COVID-19. However, we

decline to adopt any new policies to address sudden price changes. Consistent with our guidance at section 30.3.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual and subject to the requirements of § 423.120(b)(5), we permit Part D sponsors to add drugs to and remove drugs from the formulary during the plan year.

Comment: Some commenters suggested that CMS should increase the specialty-tier cost threshold by the Annual Percentage Increase (API) or medical inflation with a periodic rebalancing when the specialty-tier cost threshold represents less than one percent of claims.

Response: We thank the commenters, but we decline to adopt this recommendation because we proposed a methodology that would keep specialty tier drugs at the top 1 percent.

We are finalizing without modification our proposed methodology to increase the specialty-tier cost threshold.

A summary of the comments on increasing the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*) and our responses follow.

Comment: Most commenters supported CMS's proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). A commenter asked what the cost threshold for higher cost-sharing, specialty tier would be, and if it will be set by the plan.

Response: We thank the commenters for their support. We are not finalizing this proposal. The specialty-tier cost threshold will apply to both specialty tiers, and while Part D sponsors would not set the threshold, Part D sponsors may choose which specialty-tier drugs go on which tier, subject to our annual formulary review and approval process. However, as we noted in our May 22, 2020 HPMS memorandum entitled, "Updated Contract Year (CY) 2021 Final Part D Bidding Instructions," for coverage year 2021, we will maintain the specialty-tier cost threshold at $670, as a 30-day equivalent negotiated price. The methodology that is being finalized in this rulemaking will be in effect for coverage year 2022.

Comment: Some commenters asked whether CMS considered the effect of our proposal to increase the specialty-tier cost threshold in combination with our proposal to permit Part D sponsors to maintain up to two specialty tiers, overall, asserting that CMS may be reducing the benefits that a second specialty tier could bring to plans and Part D enrollees because a brand drug may continue to qualify for the specialty tier(s) while its generic equivalent may not.

Response: As discussed earlier in this section (section IV.E.6) of this final rule, we believe the specialty tier should consist of only the highest-cost drugs and therefore, that we should apply a methodology that takes into account rising drug costs and changes in utilization over time. There is a chance that a drug – including a generic drug – that no longer qualifies for placement on the specialty tier may be placed on a non-specialty, non-preferred brand/drug tier, which may have up to 50 percent coinsurance. We note however that this scenario exists today, where drugs are no longer eligible for specialty tier placement because they no longer meet the specialty-tier cost threshold, and Part D sponsors can choose to place them on formulary in a way that they deem best for their enrollees, provided they comply with the requirements of our formulary review and approval process under § 423.120(b). The dynamics around formulary placement of brand and generic drugs and the elements that drive those decisions are central to the core structure and function of the Part D benefit. We therefore do not believe this proposal exacerbates this issue. We also acknowledge in section IX.E.5. of this final rule that conflicting forces might limit the potential savings/benefits of this proposal. Moreover, it is important to note that drugs on a non-specialty, non-preferred brand/drug tier are subject to tiering exceptions.

Under the requirements of § 423.578(a)(6) and consistent with our guidance at section 40.5.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, non-preferred generic drugs are eligible for tiering exceptions to the lowest applicable cost sharing associated with alternatives that are either brand or generic drugs when the medical necessity criteria are met. This represents an important protection for Part D enrollees, particularly when paired with our benefit parameters that we establish on an annual

basis. Under § 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs (meaning, actuarially equivalent standard, basic alternative, or enhanced alternative benefit designs) may not exceed levels (or cost sharing thresholds) that we annually determine to be discriminatory.

We are not finalizing our proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent ingredient cost) for contract year 2021 from the previous $670 (as a 30-day equivalent negotiated price). For CY 2021, we will maintain the specialty tier threshold at $670, as a 30-day equivalent negotiated price. However, as previously described, we are finalizing our proposed methodology to determine the specialty tier threshold each year, beginning with CY 2022.

In summary, we are finalizing without modification our proposals to:

• Add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers;

• Maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier;

• Add new paragraphs § 423.104(d)(2)(iv)(D)(*1*) through (*3*) to establish a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, for plans with two specialty tiers, the higher cost-sharing, specialty tier;

• Permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the other specialty tier;

• Give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2);

• Amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv);

• Add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year;

• Add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier; and

• Add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold.

In response to comments, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drug.

These final policies will apply for coverage year 2022, and we will announce the specialty-tier cost threshold for coverage year 2022 prior to the contract year 2022 bidding deadline.

As discussed in section IV.E.2 and earlier in this section (section IV.E.6) of this final rule, to retain the policies in effect before coverage year 2022, we will:

• Amend the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022; and

• Amend § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference

placement of the definition of specialty tier at § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase "and biological products." Additionally, paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

F. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

1. Overview and Summary

Section 101 of the MMA requires the adoption of Part D e-prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA-PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. Prescribers and dispensers who electronically transmit and receive prescription and certain other information for Part D-covered drugs prescribed for Medicare Part D-eligible individuals, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

Section 119 of the Consolidated Appropriations Act requires that Part D plan sponsors implement a prescriber RTBT capable of integrating with clinicians' electronic prescribing and electronic health record systems for the real-time transmission of formulary, benefit, clinical alternative, cost sharing, and utilization management information specific to Part D plan enrollees. This requirement is to take effect once the Secretary names a prescriber RTBT standard, which has not yet occurred.

For a further discussion of the statutory basis for this final rule and the statutory requirements at section 1860D-4(e) of the Act, please refer to section I. of the February 4, 2005, Medicare Program; E-Prescribing and the Prescription Drug Program Proposed Rule (70 FR 6256).

In accordance with our regulations at § 423.160(b)(1), (2), and (5), CMS' Part D eRx program requires that Part D sponsors support the use of the adopted standards when electronically conveying prescription and formulary and benefit information regarding Part D-covered drugs prescribed to Part D-eligible individuals between plans, prescribers, and dispensers.

CMS utilized several rounds of rulemaking to update the Part D e-prescribing program. Most recently, in the May 2019 final rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Final Rule (84 FR 23832) (hereinafter referred to as the May 2019 final rule), we required that Part D plans support a prescriber electronic real-time benefit tool capable of integrating with at least one e-prescribing or electronic health record (EHR) system. The prescriber RTBT must provide its enrollees with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including enrollee cost sharing information formulary alternatives and utilization management requirements). This "prescriber RTBT" electronic transaction requirement will become effective January 1, 2021, and is expected to enhance medication adherence and lower overall drug costs by providing Part D prescribers information in real time when lower-cost alternative drugs are available.

The SCRIPT and the NCPDP Formulary and Benefits standards have already become critical components of the Part D program, and CMS believes that the recently finalized prescriber RTBT requirement at § 423.160(b)(7) will do the same by enhancing the electronic communication of prescription-related information between plans and prescribers under the Part D benefit program. In order to further enhance this communication, CMS has been monitoring the development of prescriber RTBT standards and will consider adoption of these standards in future rulemaking. While these requirements will empower prescribers, CMS also believes it is important to empower patients with information like that which will be included in the prescriber

RTBT and give them the ability to access this information either at their computer or using a mobile device.

In the February 2020 proposed rule, CMS proposed to adopt at § 423.128(d)(1)(vi), (d)(4) and (d)(5) a requirement that Part D sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, effective January 1, 2022, so as to allow both prescriber and patient to consider potential cost differences when choosing a medication that best meets the patient's medical and financial needs. CMS proposed to require that each system response value would need to present real-time values for the patient's cost-sharing information and clinically appropriate formulary alternatives, where appropriate. This requirement would include the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits, and prior authorization, applicable to each alternative medication. CMS also proposed to require that plans make this information available to enrollees via their customer service call center.

CMS received the following comments related to our proposal, in general. Our responses follow.

Comment: All commenters supported our proposal, citing the need to provide beneficiaries with actionable information about their prescription drug costs, so beneficiaries can make better informed decisions about treatment options.

Response: CMS thanks commenters for their support. CMS agrees that providing beneficiaries with information about prescription drug costs is important and that the beneficiary RTBT will help provide this information to Part D enrollees.

Comment: Some commenters requested that we delay the implementation date until January 1, 2023 to allow more time for testing the tool. Some of these commenters requested that we exercise enforcement discretion, should we choose not to delay the implementation date.

Other commenters requested that we change the implementation date to January 1, 2021 so that beneficiaries can access the benefits of the tool more expeditiously.

Response: CMS understands both the desire to ensure that the tool functions properly and that Part D enrollees have access to information about prescription drug costs. However, in order to help ensure that Part D sponsors have adequate time to implement the tool properly so that beneficiaries can access accurate information as seamlessly as possible, we have decided to delay the implementation date until January 1, 2023.

Comment: A few commenters requested that CMS provide training tools on beneficiary RTBTs to help ensure that Part D enrollees are able to use the RTBTs properly. Other commenters requested that we provide the Part D sponsors with standard language to use on their beneficiary RTBTs to help ensure that Part D enrollees are able to understand the information.

Response: CMS believes that helping ensure that Part D enrollees can use the beneficiary RTBTs and understand the information within them is of utmost importance. However, CMS wants to help ensure that plans have sufficient flexibility when implementing this requirement, since most Part D sponsors have computer applications or portals in place and are more attuned to the needs of their enrollees. In addition, the RTBTs may differ slightly by plan, so we believe that Part D sponsors are better equipped to ensure that their enrollees understand how to use the tool and the language within it.

In order to help ensure that beneficiaries understand how to use this tool, CMS considered requiring that Part D sponsors provide training to their enrollees. However, we believe this would limit our strategy of maximal flexibility for Part D sponsors in implementing this new requirement. Part D sponsors are in the best position to gauge whether or not their enrollees would benefit from training about how to use beneficiary RTBTs. Furthermore, we expect these RTBTs to be similar to the computer applications or portals that most Part D sponsors already have in place, so we do not believe that Part D enrollees will require a training to use the new tool.

Comment: Commenters requested that we require Part D sponsors to include additional information unrelated to beneficiary drug costs in the beneficiary RTBT, such as beneficiary eligibility status, the notification that beneficiaries have the right to an appeal, an explanation of the difference between out of pocket costs and premiums, and a message letting beneficiaries know that assistance programs are available to beneficiaries to help them pay their out of pocket costs.

Response: Although CMS understands the importance of keeping beneficiaries informed about these important topics, we decline to adopt this suggestion. Beneficiaries can access this information from several sources, including upon enrollment in Medicare Part D, through the Medicare & You publication, and Medicare.gov. The purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications, rather than serve as a repository of information for Part D enrollees. As previously stated, CMS seeks to allow Part D sponsors flexibility in implementing this requirement. As a result, CMS is not requiring sponsors to include information that is not directly connected to the purpose of the RTBT. However, Part D sponsors can include additional information, if they deem it helpful to their enrollees.

2. Pricing Information for the Beneficiary RTBT

As previously noted, CMS proposed to require that Part D sponsors include beneficiary-specific cost information in their beneficiary RTBTs. We proposed this requirement since we believe that sharing this information would yield greater medication adherence. In our proposed rule, we cited evidence suggesting that reducing medication cost yields benefits in increased patient medication adherence. Evidence supports that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events.[62] Given that patient cost is such a

[62] Impact of Type 2 Diabetes Medication Cost Sharing on Patient Outcomes and Health Plan Costs (2016), Julia Thornton Snider, Seth Seabury, et. Al.; The "Cost" of Medication NonAdherence: Consequences We Cannot Afford to Accept (2011), Marie A. Chisholm-Burns and Christina A. Spivey; Medication Non-adherence is Associated with Increased Medical Health Care Costs (2007), Sunanda Kane and Fadiya Shaya.

determinant of adherence, including the patient in such discussions should improve medication adherence. Further, research shows that when patients play an active role in their health care decisions the result is increased patient knowledge, satisfaction, adherence with treatment and improved outcomes.[63] Although not all patients will choose to actively participate in treatment decisions, interactive discussions between patients and physicians are correlated with improved patient satisfaction with their health care provider.[64]

We believe that bringing all of these benefits to Part D enrollees is especially important, in light of the fact that the Medicare population is becoming increasingly comfortable with technology. According to a 2017 Pew Research Center study, some groups of seniors report "owning and using various technologies at rates similar to adults under the age of 65"[65] and also characterized "82% of 65- to 69-year-olds as internet users," and found that 40 percent of seniors now own smartphones, "more than double the share that did so in 2013." As more seniors use computers and smart phones in their daily lives, it is likely that they will use electronic means to research information about their prescription medications. CMS believes that the Part D program must move to accommodate those enrollees by enhancing the way that digital technologies are currently used.

We also stated that we would consider it a best practice for beneficiary RTBTs to include cost-sharing amounts for medications if purchased at a pharmacy selected by the beneficiary, provided the pharmacy is in the plan's network. Sponsors would also be allowed to provide cost data for alternative pharmacies in the plan's network. However, due to concerns with enrollees being steered to different pharmacies, we did not propose to require that beneficiary RTBTs include pharmacy-specific cost sharing information.

In order to support maximum transparency, CMS also encouraged plans to show each drug's negotiated price (as defined in § 423.100) in the beneficiary RTBTs in addition to the

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[63] See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1855272/
[64] See https://www.ncbi.nlm.nih.gov/pubmed/11021677/
[65] Report is accessible at https://www.pewinternet.org/2017/05/17/technology-use-among-seniors/.

requirement to reflect the beneficiary's out-of-pocket cost information at the beneficiary's currently chosen pharmacy. Alternatively, if the beneficiary RTBT does not show the negotiated price, we would encourage plans to provide additional cost data comparing the beneficiary and plan cost comparisons for each drug and its alternatives. For example, if Drug A has beneficiary cost sharing of $10 and the plan pays $100, and Drug B also has a beneficiary cost sharing of $10 but the plan only pays $90, the beneficiary RTBT would reflect a difference of $0 for cost sharing and -$10 in comparative plan cost for Drug B. Providing data such as negotiated price or comparative plan costs would provide beneficiaries with a better understanding of the price differences between alternative drugs and could help provide beneficiaries with information on potential clinically appropriate alternatives that could steer a discussion with their clinician and provide the biggest savings to the beneficiary and potentially lower Part D costs overall.

Although we encouraged the inclusion of the negotiated price and other comparative information in the beneficiary RTBT, we did not propose to require the inclusion of such information. We did not propose to require this because we do not have research that shows learning the payer's rate will affect beneficiary choice if there is no effect on their payment amount. However, we solicited comment on this issue.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. In the following pages, we summarize the comments received about the pricing data to be included in the beneficiary RTBT.

Comment: Some commenters requested that CMS require the inclusion of the negotiated and net prices of medications, which is the cost of the medication after all rebates and fees are subtracted. Other commenters requested that we refrain from even encouraging the inclusion of the negotiated price, as we did in our proposed rule.

Response: CMS understands that it may be helpful for some beneficiaries to see additional pricing information, including the negotiated and net prices. However, as stated in our

November 2020 Transparency in Coverage final rule (85 FR 72158), which implements requirements for group health plans and health insurance issuers in the individual and group marketto share participant cost sharing information and the negotiated price with the participant in the form of machine readable files and paper (upon request by the participant), CMS should aim to strike a balance between illuminating some of the factors that drive drug costs and not overwhelming consumers with information that is not directly relevant to their cost-sharing liability. In the case of the beneficiary RTBT, we believe this balance is best struck through alignment with the information in the prescriber RTBT, which does not require inclusion of the negotiated or net prices. Having the same information in both tools will not only help facilitate conversations between enrollees and their providers about different medications for the enrollee, but will give the prescriber the opportunity to explain the information in the beneficiary RTBT to enrollees. Providing enrollees information about the negotiated drug prices could easily overwhelm consumers with information, since the pricing information is updated in real time using test claims transmitted to the pharmacy in order to adequately gauge what the drug price is at the time the request is made.

By contrast, in our November 2020 final rule, the requirement for group health plans and private issuers is to compile information for consumers in a file outside of the prescriber RTBT. As a result, group health plans and private issuers are only required to provide this information once – through a machine-readable file or via paper. However, if we were to require Part D sponsors to provide the negotiated and net prices in the beneficiary RTBT, Part D sponsors would be required to transmit two different claims in order to facilitate these tools – one for the prescriber RTBT and one for the beneficiary RTBT. We believe that the benefit these enrollees derive from seeing the net and negotiated prices is outweighed by the burden for plans to calculate this cost and program it into the beneficiary RTBT.

Further, since most plans have similar beneficiary RTBTs in place, we believe that plans are in the best position to gauge what information is useful to their enrollees. We intend for our

regulatory requirements to be a starting point for the beneficiary RTBTs and that plans will have the ability to add in additional information, if they believe it will helpful for their enrollees. The sole purpose of our regulatory requirements is to provide the minimum amount of information that must be included in the beneficiary RTBT, and we do not believe that including the net or negotiated prices is absolutely necessary in the beneficiary RTBTs. This approach differs from the approach in our November 2020 final rule, since Part D plans already have similar tools in place, whereas the group health plans and issuers in the private and group market do not.

Comment: Some commenters requested that CMS require Part D plans to include pharmacy and provider-specific data, so that beneficiaries can find the lowest possible price for their medications.

Response: CMS understands the importance of ensuring that beneficiaries have the appropriate tools to find the lowest price medications. However, CMS seeks to balance this desire with the desire to ensure that beneficiaries are not improperly steered away from their pharmacies and providers of choice. Since plans have the most experience in working with enrollees, we seek to give plans flexibility in implementing the beneficiary RTBT. As a result, we will not prohibit plans from displaying pharmacy and provider-specific pricing. However, we will not require plans to show this information. Therefore, we decline to accept the suggestion that we mandate that plans include this information. Instead we are finalizing our proposal to require only that Part D sponsors include the enrollee cost sharing amount, rather than the negotiated or net price.

3. Beneficiary RTBT Formulary Data

In order to fully empower enrollees to select the most appropriate medications, we proposed to require Part D sponsors to review formulary medications to determine which alternatives exist and whether those alternatives may save their enrollees money through reduced cost sharing. The sponsors would then import that information into the beneficiary RTBT.

However, since we understand that most enrollees may not have the clinical background required to accurately discern the clinical appropriateness of all alternatives, we proposed a narrow exception to this requirement, to include for example certain antibiotics which are "drugs of last resort" that are typically reserved for instances in which the patient is found to have certain drug-resistant infections, or instances in which side-effects are such that a given prescription would not typically be selected in the absence of countervailing risks that would justify risking such side-effects, or instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug. In these and other clinically appropriate instances, we stated that it may be appropriate to omit certain drugs from what is presented to the user of a beneficiary RTBT. Thus, in order to address these and other clinically appropriate scenarios, we proposed that Part D sponsors would be permitted to have their Pharmacy and Therapeutics (P & T) committees evaluate whether certain medications should be excluded from the beneficiary RTBT. In order to help ensure that this exception is narrowly construed, we proposed to allow P & T committees to exclude medications from the beneficiary RTBT only in the following situations or instances: 1) the only formulary alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, 2) for cases where medications are considered to be "drugs of last resort," 3) instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug, or 4) other clinically-appropriate instances.

We clarified that the data that we proposed to require be provided in the beneficiary RTBT must be patient-specific, clinically appropriate, timely, accurate, and devoid of commercial purposes that would adversely impact the intended functionality of promoting cost-effective beneficiary and prescriber selections of drugs. In the following pages, we summarize the comments and provide our responses and final decisions surrounding formulary data to be included in the beneficiary RTBT.

Comment: A number of commenters recommended that CMS remove the requirement for any formulary alternatives to be included on the beneficiary RTBT. These commenters expressed concern that listing these alternatives for Part D enrollees would lead to confusion among their enrollees, since beneficiaries would not be able to appropriately discern whether the medications are appropriate for them. Another commenter suggested that CMS require Part D sponsors to include alternatives that are not on plan formularies, in addition to the formulary alternatives, so that enrollees have a greater array of options.

Response: Part D sponsors are required to include medications on their formulary that provide beneficiaries with a broad range of medically appropriate drugs across an appropriate breadth of categories and classes that cover all disease states, and meet other classifications. CMS reviews these formularies annually to help ensure compliance. As a result, we believe that the medications listed on the Part D formularies should provide sufficient options for Part D enrollees without requiring alternative options for enrollees outside of the Part D formularies.

Although CMS shares commenters' concerns surrounding beneficiary confusion, we believe that limiting beneficiaries' choices to medications within their plan's formulary will help alleviate this concern. CMS believes that allowing beneficiaries the opportunity to choose from different medication alternatives within the plan's formulary strikes the right balance between ensuring that beneficiaries have adequate options for medications while not overwhelming beneficiaries with too many choices that may not be available to them. Although some enrollees may find these options overwhelming, we believe that the benefit of giving beneficiaries different medication options outweighs the risk that some beneficiaries may be overwhelmed by all the medication choices.

Comment: The majority of commenters disagreed with our proposal to allow plans to exclude formulary alternatives in clinically appropriate instances, citing the possibility that plans could use this exclusion as an opportunity to steer patients away from the most clinically appropriate medications, give rise to undue confusion in cases where the provider determines

that an excluded drug is actually appropriate, or cause plans to erroneously omit certain medications from the RTBT. However, some commenters supported this exclusion, since they believed that Part D sponsors could benefit from the additional flexibility.

Response: After considering the information provided by the commenters, we are persuaded that the potential for misuse and confusion emanating from this exclusion outweighs the benefit of additional plan flexibility. CMS continues to believe that Part D sponsors should be granted flexibility when implementing the beneficiary RTBT. However, the harm that could be caused by the potential exclusion of appropriate medications outweighs the limited benefit of granting Part D sponsors this additional flexibility in this case. Therefore, we are removing this exclusion and finalizing our proposed requirement to include all formulary alternatives in the beneficiary RTBT.

4. Rewards and Incentives for Beneficiary RTBT

In order to encourage enrollees to use the beneficiary RTBT, we proposed to allow plans to offer rewards and incentives (RI) to their enrollees who use the tool. We proposed to define use, for purposes of permitted RI, to mean logging onto either the portal or application or calling the plan's call center to ask for this information, without regard to whether the enrollee engages in a discussion with his or her prescriber or obtains or switches to any medication in response to such use. In other words, we proposed that plans that choose to offer RI must offer it to all plan enrollees who use the tool or seek to access this information via phone and must not make RI contingent upon the medical diagnosis or the type of medication a beneficiary is taking, or upon the enrollee switching medications.

We proposed to prohibit any enrollee remuneration under the guise of RI, which includes waivers of copayments and deductible amounts and transfers of items or services for free. We also proposed to prohibit plans from offering any cash or monetary donations, under the guise of RI. However, we did propose to allow for the use of gift cards, as long as they are not cash equivalents and do not encourage enrollees to further patronize the plan or any of the plan's

corporate affiliates. For purposes of this proposal, CMS proposed that gift cards that can be used like cash, for example, a VISA or Amazon gift card, to be a ‘‘cash equivalent.’’ Cash equivalents also may include, for example, instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards. This means that gas cards or restaurant gift cards would be permitted. However, a gift card that can be used for goods or services purchased from the plan would be prohibited, since that could incentivize enrollment in plans that could provide gift cards that enrollees could use at pharmacies or retail stores owned by their plan, rather than at a third-party establishment owned by a different company.

We also proposed that the RI be of nominal value, which Office of Inspector General (OIG) guidance specifies as no more than $15 per login or $75 in the aggregate annually, in accordance with OIG guidance.[66] We also proposed that the member can receive a RI for no more than one login per month. We also proposed that this expense would have to be included as an administrative expense in the bids of Part D sponsors, rather than it being considered a drug cost. We solicited comments on these limitations and on how we can ensure that these RIs will not be indirectly provided or funded by pharmaceutical manufacturers. We also solicited comments on safeguards to mitigate risks of fraud and abuse with respect to these incentives.

MA-PDs are already permitted to offer rewards and incentives for Part C benefits under our regulation at § 422.134, which permits plans to offer health-driven rewards and incentives that are designed to encourage enrollees to participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We propose to adopt Part C’s ban at § 422.134(b) on discrimination for Part D RI that plans offer to encourage the use of the beneficiary RTBT. We therefore proposed to require that if a Part D plan sponsor offers RI, it must be available to all of the plan’s enrollees that log into the plan’s portal or call the plan’s call center, without discrimination based on a prohibited basis;

[66] Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries, Office of Inspector General (2016).

under applicable law, prohibited bases of discrimination include the enrollee's proficiency in English, race, color, national origin, sex, age, disability, chronic disease, health status, or other basis prohibited by law.

We proposed to add this provision to our regulations at § 423.128 by amending paragraph (d) to add paragraphs (4) and (5). Paragraph (4) would address the beneficiary RTBT and paragraph (5) would address the rewards and incentives for use of the beneficiary RTBT.

Because of the safeguards included in the aforementioned proposals, including requiring that the rewards and incentives be non-cash equivalents, we believe the RI presents a low risk of fraud and abuse and is unlikely to compromise the integrity of the program.

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters supported the use of rewards and incentives for this provision. However, some of these commenters requested that CMS allow use of Amazon gift cards for the beneficiary RTBT, since they are a popular incentive for beneficiaries. The commenters disagreed with our classification of Amazon gift cards as cash equivalents, since they can only be used when shopping on Amazon.com or in Whole Foods.

Response: CMS continues to believe that Amazon gift cards fall under the definition of cash equivalents. In their final rule entitled "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," published on December 7, 2016, (81 FR 88393), the OIG states that items that can be used like cash (such as a general purpose debit card) constitute cash equivalents. In addition, we seek to help ensure consistency across CMS rulemaking, and CMS has previously defined cash equivalents to include Amazon gift cards. Please see final rule entitled "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017" published on December 31, 2019.

Although we understand the desire to use incentives that enrich the lives of beneficiaries, CMS must balance this desire against the increased fraud and abuse risk that exists when cash equivalents, such as a general purpose debit card or Amazon gift card are offered. As a result, we prohibit the use of Amazon gift cards as an RI under the beneficiary RTBT.

However, we seek to empower Part D sponsors to ensure that beneficiaries are motivated to use the RTBT, especially given the aforementioned potential benefits of the RTBT, including medication adherence and improved patient satisfaction. As a result, we are not finalizing our proposed requirement that the rewards and incentives be nominal in value and thus be limited to $15/login and $75/year. Rather, we defer to the judgment of Part D sponsors as to what they consider to be a reasonable amount to offer their enrollees. As previously mentioned, we seek to grant flexibility to Part D sponsors as they are in the best position to judge the needs of their enrollees.

CMS understands that this standard differs from what is considered appropriate under the Part C rewards and incentives program. The goal of the Part C rewards and incentives program is to promote healthy behaviors. By contrast, the goal of the rewards and incentives program for the beneficiary RTBT is to promote use of the tool, which are intended to lead to the aforementioned potential benefits of the RTBT, including medication adherence and decreasing overall drug costs. Because these goals differ and the value of use of the tool cannot be easily quantified, the Part C limit on rewards and incentives, which requires that the value of the reward and incentive not exceed the value of the activity itself, is not appropriate in this context of the Part D beneficiary RTBT. As a result, CMS is finalizing the limit for the rewards and incentives to be the amount Part D sponsors believe to be reasonable, rather than the Part C limit on rewards and incentives or a nominal amount. The other aspects of the RTBT rewards and incentives program are being finalized as proposed.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, w. e are finalizing our proposed provisions at §§

423.128(d)(4) and (5) with several modifications. First, we are adding a January 1, 2023 applicability date to the regulation text at paragraph (d)(4) to reflect that this provision will not apply until that date. Second, because we are requiring that plans include all formulary medication alternatives, rather than only the alternatives that are clinically appropriate, we are modifying the language at § 423.128(d)(4)(ii) to require all formulary medication alternatives to be included. sSince we will be allowing plans to determine what they believe to be reasonable in determining the dollar value of the rewards and incentives, we are modifying the language at 423.128(d)(5)(i) to replace the word "nominal" with "reasonable" to clarify that the new limit for the value of the rewards and incentives is what plans consider to be a reasonable value, rather than an amount that OIG has interpreted to be nominal. Because plans will be determining what they deem to be reasonable, rather than an amount that OIG has interpreted to be nominal, we are removing the limitation at § 423.128(d)(5)(ii) on offering rewards and incentives for only one login per month.

G. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts CMS enters into with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at § 423.514. We proposed to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements.

Collecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand how the measures are applied, whether uniformly or specific to pharmacy type. This effort may also explain if there is a pharmacy performance problem, as

pharmacy price concessions (financial penalties incurred) after the POS have continued to grow annually. Knowledge of the industry's pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies. Once collected, we stated that CMS would publish the list of pharmacy performance measures reported to increase public transparency.

We encouraged the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We also solicited comment on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for instituting potential Part D Star Ratings metrics related to these measures. Finally, we solicited comment on the data elements, timeline, and method of submission for the reporting of pharmacy performance measures.

We received the following comments and our response follows:

Comment: The vast majority of comments were supportive of the proposal for CMS to establish a reporting requirement to collect pharmacy performance measures used by Part D sponsors in their network pharmacy contracts. Virtually all of the supportive comments shared the opinion that the current pharmacy performance measures and processes were either flawed, opaque or both. They believed the collection of this information would spur transparency and reveal the need for standardized measures via an industry driven consensus process facilitated by an experienced and neutral third-party.

Response: We appreciate the support for the proposal to establish a requirement for Part D sponsors to disclose pharmacy performance measures to CMS. We agree that the information should provide transparency and help industry stakeholders come to a consensus on measures.

Comment: A number of commenters believed that if CMS made the pharmacy performance measures used by Part D sponsors public it would result in a loss of leverage and flexibility for sponsors in their negotiations with network pharmacies. Other concerns were that it would stifle innovation and be harmful to market competition. A commenter requested that the measures only be shared with the involved parties. Another added that, if universal performance thresholds are applied, Part D sponsors would lose their ability to effectively negotiate performance programs with network pharmacies when true differences in performance may exist. Another believed the publication of performance measures without context could mislead patients about the performance of their pharmacies. A couple of commenters stated that the information was sensitive and that making it public would be harmful to market competition; believing it inappropriate to make sponsors' performance measure thresholds public.

Response: We remind commenters that in the proposed rule we did not propose universal performance thresholds, but rather proposed to collect plans' pharmacy performance measures as an additional reporting section of our Part D reporting requirements. Given the growing magnitude of pharmacy price concessions based on performance measures in Part D, we believe it is important to provide transparency to the public regarding the measures in use. In addition, we believe that publishing a list of currently used pharmacy performance measures will promote the development of consensus-built standards by the industry that are transparent and equitable across various pharmacy types and patient populations, and support value-based care. Creating a "level playing field" to measure pharmacy network performance should not pose an obstacle to flexibility, innovation or competitiveness. Rather, a fair, more accurate and transparent system of measuring the strengths or weaknesses of a plan's network pharmacies should encourage both plans and the pharmacies within their respective networks to be innovative, flexible and competitive in how they use the data collected. Accurately identifying poorly performing pharmacies and well-performing pharmacies should encourage, when practical, a sharing of top

pharmacy best practices' throughout a plan's network that would ideally enhance a plan's competitiveness in the marketplace.

Comment: The large majority of commenters agreed with the reporting requirement proposal, but noted concerns related to industry burden, need for more industry input, that any elements or criteria be subject to rulemaking, and that a reasonable timeline for implementation be given.

Response: As stated in the proposed rule, we are dedicated to the involvement of the industry in the development of this requirement. After publication of this final rule to establish the requirement that sponsors disclose pharmacy performance measure information to CMS, any new elements added to the Part D reporting requirements (OMB 0938-0992) to implement this requirement would result from industry feedback through 60- and 30-day public comment periods in the **Federal Register** and approval through the Office of Management and Budget (OMB) Paper Reduction Act (PRA) process. As with any new elements added to the Part D reporting requirements, we believe the opportunity to provide comment through the PRA process will allow adequate input from the public and the industry. We also agree that to implement this provision we need to ensure the timeline and burden are reasonable for all parties involved. We will take into consideration the feedback received in response to the proposed rule when putting forth a timeline for implementation and potential elements for public comment.

Comment: We received one comment that warned that implementing a standard set of performance measures held the potential of narrowing pharmacy networks, thereby impacting some pharmacies and the options available to beneficiaries. Other commenters, while expressing support for standardization of measures in principle, requested that sponsors not be locked into only specific measures.

Response: We did not propose to implement a standard set of performance measures nor did we make any proposals with respect to requiring the use of any particular measures. Rather,

in the proposed rule, we encouraged industry to come to a consensus on a standard set of pharmacy performance measures.

Comment: A few commenters, while supportive of the industry standardizing pharmacy performance measures, cautioned against placing too many exacting limits on the performance measures, and stated that sponsors should retain the ability to use metrics beyond those decided by a third-party facilitator such as, but not limited to, the Pharmacy Quality Alliance (PQA), provided such measures are transparent to CMS and pharmacies.

Response: We thank the commenters for their comments. We reiterate that we did not propose to standardize pharmacy performance measures in the proposed rule. We would expect that if through an industry consensus a standard set of pharmacy performance measures is established, it would be through a similar transparent and consensus process that additional measures would be added. We note, however, that transparency is of little consequence if the measures or the corresponding thresholds for that measure are ill-suited for the type of pharmacy or patient population that is being evaluated.

Comment: We received a few comments regarding our request for feedback on recommendations on measures to consider for use in the Part D Star Ratings related to the uptake or evaluation of pharmacy performance measures. A commenter believed it premature to consider specific metrics for a Star Ratings program, and another opposed the idea, believing that the proposed use of Star Ratings for pharmacy performance would not be meaningful to Medicare beneficiaries who judge pharmacy performance on a highly personalized basis. Other commenters strongly supported our proposal with one asking the agency to follow its traditional approach when first introducing Star Ratings and report the results on the display page. We received a comment that requested that any future pharmacy performance measures be developed in a way that directly ties to the Part D Star Ratings program.

Response: We appreciate the comments received and will consider them for any potential future development of measures based on pharmacy performance measure information.

We note that we believe it is not premature to discuss potential Star Ratings as there would be a natural outgrowth to the development of standardized pharmacy measures. While we agree with the commenter that the selection of a pharmacy by a Medicare beneficiary is often a highly personalized choice, we believe that creating a rating system that leverages this plan-reported data could offer the beneficiaries additional information about the performance of pharmacies in the sponsors' pharmacy network.

We agree with the commenter that requested we follow the regulatory process for the introduction of new Star Ratings measures. CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule (83 FR 16725 through 83 FR 16731), published in April 2018, for performance periods beginning with 2019; that final rule lays out the methodology for the 2021 Star Ratings and beyond. CMS will continue to solicit feedback on new measure concepts as well as updated measures through the process described for changes in, and adoption of, payment and risk adjustment policies in section 1853(b) of the Act. We will also continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. As specified at § 422.164(c)(2)-(4), § 423.184(c)(2)-(4), § 422.164(d)(2), and § 423.184(d)(2), new measures and measures with substantive specification changes must remain on the display page for at least 2 years prior to becoming a Star Ratings measure. We appreciate the comment that we develop any future pharmacy performance measures in a way that can be directly tied to the Part D Star Ratings program.

Comment: A few commenters responded to our solicitation for feedback regarding the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent and/or rural pharmacies. Most comments suggested that smaller pharmacies be exempt entirely from all performance measures or subject to a modified approach. A commenter indicated that a voluntary set of

measures, or a custom measurement set that is more applicable and feasible for smaller pharmacies to report (for example, patient counseling, medication therapy management) be used.

Response: We thank the commenters for their recommendations and will take them into consideration.

Comment: A commenter stated that pharmacies should have the ability to appeal results of their performance measures.

Response: We appreciate the comment regarding appeal rights; however, we did not propose to adopt any performance measures, and therefore did not propose an appeals procedure.

Comment: In response to our solicitation for comments on the proposed list of potential data elements there were two primary objections made by commenters. Some commenters opposed the use of retrospective data that could include success/failure thresholds, and average scores or statistics that may reveal sensitive information regarding contractual arrangements. There were no comments supportive of the proposed rule specifically on the data elements.

Response: We appreciate the comments. In the proposed rule, we recommend and encourage industry to continue, through a neutral third-party facilitator, creating and testing potential pharmacy performance measures based on industry consensus. If an industry-wide consensus is reached on a set of standardized measures it follows that part of the process of reaching consensus will be determining what should and should not be reported retrospectively, and what would and would not be deemed sensitive contractual information between a sponsor and its pharmacy network.

Based on these comments, we are finalizing our proposal to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements, with one modification to make the provision applicable starting January 1, 2022.

H. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

We proposed regulations for withdrawing or dismissing Part C organization determination and reconsideration requests and Part D coverage determination and redetermination requests. We also proposed regulations for withdrawing or dismissing Part C and Part D independent review entity (IRE) reconsiderations. We also proposed to apply these provisions to requests for integrated organization determinations and reconsiderations at §§ 422.631 and 422.633. The proposals specifically addressed under what circumstances it would be appropriate to dismiss a coverage request or appeal at the plan or IRE level. We also proposed rules for how a party may request to withdraw their coverage request or appeal at the plan or IRE level. A withdrawal of a request is when the party that initiated the request voluntarily decides that a decision on their request is no longer needed, and the party communicates that desire to the plan to stop consideration of the request for determination (or reconsideration). A dismissal of a request is when a plan decides to stop consideration of a request before issuing a decision. The effect of both a withdrawal and a dismissal is that the plan does not proceed with making a substantive decision on the merits of the coverage request.

Specifically, we proposed that:

• In new §§ 422.568(g), 422.631(e), and 423.568(i), we proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when any of the following apply--

++ The individual or entity making the request is not permitted to request an organization determination or coverage determination.

++ The plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination.

++ The enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; we explained in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ The individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan.

• In §§ 422.570(g) and 423.570(f), we proposed to permit a plan to dismiss an expedited organization determination or coverage determination, consistent with the proposed requirements at §§ 422.568 and 423.568, respectively. Applicability of these procedures to expedited integrated coverage determinations was proposed at § 422.631(e).

• In §§ 422.582(f), 422.633(h), and 423.582(e), we proposed to permit a plan to dismiss (either entirely or as to any stated issue) a request for the second plan level decision (that is, reconsideration, integrated reconsideration or redetermination) when any of the following apply --

++ The individual or entity making the request is not a proper party to the reconsideration, integrated reconsideration, or redetermination under the applicable regulation; we explained that this proposal would authorize dismissal when the individual or entity making the request is not permitted to request a reconsideration, integrated reconsideration, or redetermination.

++ When the plan determines the party failed to make a valid request for a reconsideration, an integrated reconsideration, or a redetermination that substantially complies with the applicable regulation for making a valid request for reconsideration or redetermination.

++ When the party fails to file the reconsideration, integrated reconsideration or redetermination request within the proper filing time frame in accordance with the applicable regulation.

++ When the enrollee dies while the reconsideration or redetermination is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration or redetermination. We explained in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ When the individual or entity submits a timely written request to withdraw their request for a reconsideration or redetermination.

• At new § 422.584(g), we proposed to permit a plan to dismiss an expedited reconsideration using virtually identical language as for the proposed requirements at § 422.582. At new § 423.584(f), we proposed to permit a plan to dismiss an expedited redetermination by cross referencing § 423.582. Applicability of these procedures to expedited integrated coverage determinations was described in proposed § 422.633(h).

• At new §§ 422.592(d) and 423.600(g), we proposed to permit the Part C and Part D IRE to dismiss a request when any of the following apply—

++ The individual or entity is not a proper party under § 422.578 in the case of a Part C reconsideration or is not permitted to request a reconsideration by the IRE under § 423.600(a) in the case of a Part D reconsideration.

++ The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation.

++ When the enrollee dies while the reconsideration request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration. We explained

in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage.

++ When the individual or entity submits with the independent review entity a timely written request for a withdrawal of the reconsideration.

• In §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) we proposed that a written notice of the dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action; this would include the individual or entity who made the request. The notice must include certain information, as appropriate, including applicable appeal rights (that is, request to vacate dismissal, review of the dismissal).

• In §§ 422.568(i), 422.582(h), 422.592(f), 422.631(g), 422.633(j), 423.568(k), 423.582(g), and 423.600(i), we proposed that a dismissal may be vacated by the entity that issued the dismissal (that is, MA organizations, applicable integrated plans, Part D plan sponsors, and the IRE) if good cause for doing so is established within 6 months of the date of the dismissal.

• In §§ 422.568(j), 422.631(h), and 423.568(*l*), we proposed that the dismissal of the organization determination or coverage determination is binding unless it is modified or reversed by the MA organization, applicable integrated plan, or Part D plan sponsor, as applicable, upon reconsideration or vacated under the provisions we proposed for vacating dismissals.

• At new §§ 422.582(i), 422.633(k), and 423.582(h), we proposed that the dismissal of the reconsideration or redetermination is binding unless the enrollee or other valid party requests review by the IRE or the dismissal is vacated under the applicable regulation.

• At new §§ 422.592(g) and 423.600(j), we proposed that a dismissal by the IRE is binding and not subject to further review unless a party meets the amount in controversy threshold requirements necessary for the right to a review by an administrative law judge or

attorney adjudicator and the party files a proper request for review with the Office of Medicare Hearings and Appeals as outlined in §§ 422.600, 422.602, and 423.600(j), as applicable.

• At new §§ 422.568(k), 422.592(h), 422.631(i), 422.633(g), 423.568(m), and 423.600(f), we proposed that a party that makes a request may withdraw its request at any time before the decision is issued by filing a written request for withdrawal. Each proposed regulation paragraph identifies the entity (that is, the MA organization, the applicable integrated plan, or the Part D plan) with which the request for withdrawal must be filed.

We also proposed a change that applies to Part C only, given that the current rules do not include a process for an enrollee or other party to request IRE review of an MA organization's reconsideration (because review by the IRE of an adverse reconsidered determination is automatic). Specifically, we proposed to add a new paragraph (i) (mistakenly identified as a new paragraph (h) in the preamble of the February 2020 proposed rule) to § 422.590 that would give the enrollee or another party to the reconsideration the right to request review by the independent entity of an MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g). In new paragraph (i) of § 422.590 we proposed that a request for review of such a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice. Under existing rules at § 422.590(a)(2), (b)(2), (c)(2), (d), (e)(5), and (g)[67], if the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination or fails to meet the timeframe for making a reconsidered determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a reconsideration (or no later than the expiration of an applicable extension). These regulations that require a case to be automatically sent to the independent

[67] We note that § 422.590 was extensively amended by the April 2019 final rule, effective January 1, 2020.

entity do not apply in the case of a dismissal of a request for a reconsideration because the MA organization is not making a substantive decision on the merits of the request.

As a corollary to this proposal, we also proposed to revise paragraph (a) of § 422.592 to add that, consistent with proposed § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests. As noted earlier in this section of the preamble, this new paragraph (i) to § 422.590 was mistakenly identified as new paragraph (h) in the preamble of the February 2020 proposed rule; this incorrect citation at § 422.592(a) has been corrected in this final rule to correctly refer to § 422.590(i). Further, we proposed to add a new paragraph (i) at § 422.592 to state that the independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review. In this final rule, we add a reference to § 422.590 at § 422.592(i) to state if the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590.

We also proposed a change applying to Part D only, given that the current rules do not include a process for enrollees to request IRE review of plan sponsor dismissals of redetermination requests. We proposed to add a new paragraph (f) at § 423.582 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the Part D plan sponsor's dismissal of a request for a redetermination. As a corollary to this proposal, we also proposed to add paragraph (j) at § 423.590 to state that, consistent with proposed § 423.584(f), an enrollee can request review of a Part D plan sponsor's dismissal of a redetermination request by the independent entity. Finally, we proposed to add a new paragraph (k) at § 423.600 to state that if the independent entity determines that the Part D plan sponsor's dismissal was in error, the independent entity would reverse the dismissal and remand the case to the plan for a redetermination on the merits of the case.

We received the following comments on the proposals related to dismissal and withdrawal of Medicare Part C organization determination and reconsideration and Part D coverage determination and redetermination requests.

Comment: Numerous commenters opposed the proposed language that required a party to submit a written request in order to withdraw requests for organization determinations, coverage determinations, reconsiderations, and redeterminations. Commenters noted that this language indicated that verbal withdrawal requests would not be accepted. Commenters referenced CMS guidance that states, in the "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance" (Effective January 2020), at section 40.14, that a plan may accept verbal requests to withdraw a request for an organization or coverage determination. Additionally, commenters noted the same guidance states, in section 50.4, that a plan may also accept verbal requests to withdraw a request for a reconsideration, provided that the plan mails a written confirmation of the withdrawal to the party within 3 calendar days from the date of the verbal request. Commenters recommended removing the requirement for a written request to withdraw appeal requests in order to maintain consistency with the sub-regulatory guidance and current industry practice, and to reduce burden on enrollees and plans. Commenters supported the current practice of requiring a written confirmation be mailed to the party within three calendar days from the date of the verbal request.

Response: CMS thanks the commenters for their perspective and feedback. The proposed provisions were intended to generally model the current provisions regarding dismissal and withdrawal of requests for appeal codified in 42 CFR part 405, subpart I (see §§ 405.952 and 405.972) because under § 422.562(d)(1), unless subpart M provides otherwise, and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate. Part 405, subpart I states that a party may withdraw a request by filing a written and signed request for withdrawal (see, §§

405.952 and 405.972). Accordingly, we proposed that a request for withdrawal be made in writing.

However, the primary goal of codifying dismissal and withdrawal processes in regulation is to codify what we believe to be the current practices related to dismissal and withdrawal of Part C organization determination and reconsideration requests and Part D coverage determination and reconsideration requests, including those applicable to the Part C and Part D IRE. As commenters pointed out, current guidance permits plans to accept a request for withdrawal that has been made verbally. Accordingly, in response to these comments, we are finalizing the regulation changes with revisions to permit verbal requests to withdraw requests for organization determinations, coverage determinations, reconsiderations, and redeterminations are permitted under this final rule.

In response to the comments asking that verbal dismissal and withdrawal requests not be prohibited by regulation, we are finalizing the proposed changes, with modifications, to permit withdrawal requests to be made verbally. Specifically, the word "written" is not being finalized in the following provisions in this final rule: §§ 422.568(g)(4), 422.568(k), 422.582(f)(5), 422.592(d)(4), 422.592(h), 422.631(e)(4), 422.631(i), 422.633(g), 422.633(h)(5), 423.568(i)(4), 423.568(m), 423.582(e)(5), 423.600(f), and 423.600(g)(5). Additionally, in this final rule we are finalizing revisions to §§ 422.582(e) and 423.582(d) to remove the word "written" from the current regulation text describing a withdrawal of a request for a reconsideration. While this is a variance from the fee-for-service rules at 42 CFR part 405, subpart I (see §§ 405.952 and 405.972) upon which these final rules are generally modeled, this approach is consistent with existing Parts C and D guidance on these processes which allow for verbal withdrawal requests for organization determinations, coverage determinations, reconsiderations, and redeterminations.

Comment: We received a number of comments on the proposals to require a plan to dismiss a request for organization determinations, coverage determinations, reconsiderations, and

redeterminations when the individual or entity who requested the review submits a timely written request for withdrawal. Specifically, commenters were concerned about the requirements in §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) that would require plans to provide written notice to the parties of a dismissal, including instances where a party asks to withdraw their request for an organization determination, coverage determination or appeal. Commenters also noted that by considering a timely request for withdrawal as a circumstance under which a plan may dismiss a request, CMS is causing confusion between and conflation of withdrawals and dismissals. Commenters noted that the withdrawal process is different from the dismissal process and recommended that CMS exclude references to withdrawals in the list of circumstances under which a plan or IRE may dismiss a request for an organization determination, coverage determination or appeal under proposed §§ 422.568(g), 422.582(f), 422.592(d), 423.568(i), 423.582(e) and 423.600(g).

Response: CMS thanks the commenters for their perspective and feedback. The proposed provisions were intended to generally model the current provisions regarding dismissal and withdrawal of requests for appeal codified in part 405, subpart I (see §§ 405.952 and 405.972) because under § 422.562(d)(1), unless subpart M provides otherwise and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate.

The reasoning behind adopting the proposed provisions at §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) related to providing written notice to the parties of a dismissal, which are generally modeled on §§ 405.952 and 405.972, is to preserve the rights of other proper parties to the decision if one party submits a withdrawal request; other parties may wish to pursue the appeal. For example, a physician may file an organization determination request on behalf of the enrollee and then later decide to withdraw the request because the physician better understands the reason for denial after further

research. The plan would then dismiss the physician's request and issue a dismissal notice to the physician and enrollee. The enrollee is still a party to the request for an organization determination and may have an interest in having that organization determination process continue so that the plan issues a complete decision in accordance with §§ 422.566 and 422.568 despite the physician's withdrawal of the physician's request. Under our proposed provisions, the enrollee could then file a request to review the dismissal at the next level and explain that he or she wants a decision to be reached and issued. CMS regulations do not require all parties to file a request for a determination or reconsideration in order for them to remain parties to the appeal; issuing a notice of dismissal to all parties when the dismissal is based on the withdrawal request from the party that initially filed a request acknowledges that involvement.

Commenters also stated that they believe the requirement to issue a notice of dismissal when a party requests a withdrawal may cause confusion from both a reporting standpoint and a notification standpoint. CMS does not believe this proposal will cause confusion. For reporting, purposes, withdrawals and dismissals will remain distinct categories. Further, a notice of dismissal must contain the reason for dismissal; accordingly, the reason for dismissal in such cases would be the withdrawal of the request for the organization determination, coverage determination, reconsideration, or redetermination by a proper party to the request. Further operational guidance will be issued by CMS, as necessary.

Comment: Several commenters noted that the circumstances for dismissal of a request for an organization determination, coverage determination, reconsideration, or redetermination listed in §§ 422.568(g), 422.570(g), 422.582(f), 422.584(g), 422.592(d), 422.631(e), 422.633(h), 423.568(i), 423.570(f), 423.582(e), 423.548(f), and 423.600(g) are permissive rather than mandatory, in that the word "may" is used. The commenters noted that all of the circumstances listed in the regulation imply the party requesting the reconsideration is either not a proper party or no longer has a financial interest in pursuing the reconsideration. The commenters

recommend that CMS make the dismissal due to these circumstances mandatory and not permissive.

Response: It was not CMS' intent that the proposed regulatory language related to dismissals for these reasons be permissive. In this final rule, we are finalizing the provisions at §§ 422.568(g), 422.570(g), 422.582(f), 422.584(g), 422.592(d), 422.631(e), 422.633(h), 423.568(i), 423.570(f), 423.582(e), 423.584(f), and 423.600(g) without the word "may" to be clear on this point and to better align these provisions with §§ 405.952(b) and 405.972(b).

Comment: Several commenters noted that, under the proposed provision, written notice of a dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action. The commenters requested further guidance from CMS regarding applicable timeframes that would apply to this notice as well as the template or information that must be included.

Response: With respect to the commenter's request for guidance regarding the timeframes applicable to a notice of dismissal, the existing regulatory timeframes for issuing a decision notice when a substantive decision is made on a request will also apply if a request is dismissed under these final rules. In other words, a decision to dismiss a request is a determination, albeit a procedural one, on the type of request that was made and is subject to the decision notice timeframes at §§ 422.568(b) and (c), 422.572(a), 422.590(a), (b), (c), and (e), 422.631(d)(2), 422.633(f), 423.568(b) and (c), 423.590(a), (b), and (d) and 423.600(d). As an example, if an enrollee requests a standard reconsideration for a medical item or service pursuant to § 422.582 and the plan dismisses the request under the provisions at § 422.582(f) set forth in this final rule, the enrollee must be notified of the dismissal no later than 30 calendar days from the date the plan receives the request for a standard reconsideration under the provisions at § 422.590(a). A model Notice of Dismissal of Appeal Request can be found in section 50.9 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective January 1, 2020). As necessary, additional operational guidance related to

dismissal procedures will be issued by CMS. We note that the regulatory provisions we are finalizing regarding dismissals include specific provisions addressing the content of the notice of the dismissal (for example, §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h)); therefore, the current regulations governing the content of notices of substantive decisions on organization determinations, reconsiderations, integrated organization determinations, integrated reconsiderations, coverage determinations, and redeterminations and reconsiderations do not apply to dismissal notices. We also note that the proposed provisions addressing the content of the notice of dismissal for integrated organization determinations at § 422.631(f) were inadvertently incomplete. In the final rule we have revised the proposed text of § 422.631(f) to align with the analogous provisions for non-integrated organization determinations at § 422.568(h).

Comment: A commenter noted that CMS proposed that an MA plan may properly dismiss an organization determination if "the individual or entity making the request is not permitted to request an organization determination under § 422.566(c)." The commenter believes the referenced regulation, § 422.566(c), is too vague and this authority to dismiss a request on this basis will lead to beneficiaries being denied fair organization determinations. Specifically, the commenter noted that hospitals are often told by MA plans that a rehabilitation physician seeking to admit a patient to an inpatient rehabilitation hospital/unit cannot participate in organization determinations with MA plans. The commenter believes that the rehabilitation physicians that are precluded from participating are the same rehabilitation physicians required to perform the de facto prior authorization process required by Medicare. The commenter asked CMS to consider clarifying § 422.566(c) to allow any physician familiar with the patient's care needs, like a rehabilitation physician, to request an organization determination.

Response: CMS believes that the existing provisions at § 422.566(c) are sufficiently clear regarding who may request an organization determination, which include any provider that

furnishes, or intends to furnish, services to the enrollee. As such, under the commenter's example, if a rehabilitation physician furnished or intended to furnish a service to an enrollee, the physician is permitted to request an organization determination pursuant to this regulation under §§ 422.568 and 422.570. Further, § 422.578 provides that a physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in § 422.582; a physician acting on behalf of an enrollee may also request an expedited reconsideration as described in § 422.584.

Comment: Several commenters requested that CMS structure the Part C and Part D regulatory text the same way where possible, for clarity. A commenter noted by example that in § 422.584 (Expediting certain reconsiderations) CMS repeats the rules from a different section while § 423.584 (Expediting certain redeterminations) cross refers to them.

Response: CMS strives for clarity in the structure of the Part C and Part D regulatory text. We are finalizing the amendment to § 422.584 using a cross reference to rules in § 422.582 as opposed to repeating regulation text related to dismissals that is also applicable to the dismissal of expedited requests. With this change, the structure of the Part C and Part D regulation text will be in parity.

Comment: Several commenters expressed concern that the proposed regulations allow dismissal or withdrawal of requests that are never valid in the first place. The commenters believe that requests that are invalid to begin with cannot be dismissed or withdrawn. The commenters believe CMS should not continue with the plan allowances to dismiss a case that should not have been started in the first place.

Response: CMS recognizes that there may be invalid requests. However, whether a request is initially valid or not is a determination a plan makes upon receiving and reviewing a request for an organization determination. When a plan receives a request for an organization determination that it believes to be invalid, the plan refuses to approve, provide or pay for the

requested services. Such refusal is an action that is considered an organization determination under § 422.566(b). Parties to an organization determination may request that the determination be reviewed under § 422.578 and § 422.592. The scope of the 42 CFR part 422, subpart M regulations is, in part, to set forth the appeal process for MA enrollees with respect to organization determinations. Removing appeal rights from enrollees who receive an organization determination is antithetical to the purpose and scope of these regulations. The very purpose of these provisions is to provide a process and procedure (that is, dismissal) for the plan to dispense with invalid cases by issuing a procedural decision while also preserving an enrollee's right of review to a plan decision.

Comment: Two commenters responded to our request for comments regarding whether the proposed rules would create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. The commenter noted that Medicare determination and coverage processes may be different than Medicaid, and therefore, if medical care or services are not covered by Medicare, but are covered by Medicaid, withdrawing the appeal is an effective way to minimize the administrative burden of appeals in Medicare.

Response: CMS thanks the commenters for their feedback. We agree that for non-integrated plans that operate separate Medicare and Medicaid appeals processes, if an appeal concerns an item or service that is only coverable by Medicaid, withdrawing a Medicare appeal can reduce administrative burden. However, for applicable integrated plans that will follow the unified process established in §§ 422.629 – 422.634, one single coverage determination and appeals process applies to all requests for Medicare and Medicaid items and services covered by the plan, making withdrawal or dismissal of an appeal of a coverage denial inappropriate when there may be Medicaid coverage available from the applicable integrated plan. Applicable integrated plans must take into account both Medicare and Medicaid coverage available under the plan when making an integrated organization determination or integrated reconsideration.

Comment: Several commenters noted that proposed § 422.590(i) states "the enrollee or other party has the right to request review of the dismissal by the independent entity." The commenters suggested the language be clarified to reflect it is the enrollee or other "proper party under § 422.578" so as to be consistent with § 422.592, which allows dismissals of requests for reconsideration if the individual requesting the reconsideration is not a proper party.

Response: We are finalizing the amendment to § 422.590(i) and § 423.590(j) with revised text to clarify that only proper parties under § 422.578 and § 423.580, respectively, have the right to request review of the dismissal by the independent entity.

Comment: Several commenters noted that CMS proposed to permit a plan to dismiss a request for a coverage determination in four specifically listed situations (that is, when any of the following apply: the individual or entity making the request is not permitted to request an organization determination or coverage determination, the plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination, the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; or the individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan). The commenters requested clarification if this list is exhaustive or if there may be other scenarios under which a plan may dismiss a case.

Response: As noted above, we are clarifying in this final rule that a plan must dismiss a request for the reasons set forth at §§ 422.568(g), 422.582(f), 422.592(d), 423.568(i), 423.582(e) and 423.600(g). As explained in the proposed rule, we believe that codification of these procedures, including the scenarios in which a plan issues a dismissal, will reduce confusion and promote consistent and proper handling of withdrawals and dismissals. We do not believe there are other scenarios where it would be appropriate to require that a request be dismissed under

these final rules. However, if program experience once these rules have been implemented reveals other appropriate scenarios for requiring that a request be dismissed, we will take that into consideration for future rulemaking.

Comment: Several commenters noted these proposed regulations have highlighted the confusing differences in terminology between the initial levels of appeal for the Fee-For-Service Medicare Program, MA organizations, and Part D plans appeals. The commenters recommended that CMS align the appeal terminologies to avoid provider confusion and burden. For example, the initial level of appeal should have the same name for all programs, rather than redetermination for Fee-for-service and Part D and reconsideration for MA appeals.

Response: CMS appreciates these comments. We note that the appeal terminologies mirror the terms set by statute, specifically Social Security Act section 1852(g)(2) for Part C appeals, Social Security Act section 1860D-4(g) for Part D, and Social Security Act section 1869(a)(3) for Parts A and B. It is beyond the scope of this final rule to revise terminology across the Fee-for-Service, Part C, and Part D program regulations.

Comment: A commenter noted that under proposed § 422.592(i), if the IRE determines that the plan's dismissal was in error, the dismissal would be vacated and remanded to the plan for reconsideration. The commenter further noted that there is no timeframe indicated by which the plan is required to issue a decision on the remanded appeal. To ensure consistent deadlines CMS should specify that the deadlines enumerated in § 422.590 apply to remanded appeals.

Response: CMS appreciates the comment. We have modified the regulation text at § 422.592(i) to clarify that if the independent entity vacates the dismissal and remands the case to the plan for reconsideration, the reconsideration must be conducted by the plan consistent with § 422.590, which includes applicable adjudication timeframes. Similarly, we have modified the regulation text at § 423.600(k) to clarify that if the independent entity vacates the dismissal and remands the case to the Part D plan sponsor, the reconsideration must be conducted by the plan sponsor consistent with § 423.590.

Comment: A commenter noted that CMS proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when the plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination. The commenter requested CMS clarify what is considered a 'valid' request.

Response: The regulations define what constitutes a valid request. For example, with respect to a request for a standard organization determination, a valid request would be one that substantially complies with § 422.568(a); the regulation we are finalizing at § 422.568(g)(2) cross references § 422.568(a) as establishing the standard for a request to be a valid one. Related guidance can be found in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective January 1, 2020).

Comment: A commenter noted that CMS proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination. The commenter believed this is stating that a plan would dismiss a pre-service request if the enrollee dies, as it would no longer be valid, and requested further clarification.

Response: We clarify that these rules apply to a post-service request for payment as well as to pre-service requests for coverage. CMS proposed to permit a plan to dismiss a request for the initial plan level decision when the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination. The death of the enrollee alone is not sufficient to dismiss a request. There must also be no remaining financial interest of the enrollee's spouse or estate in the case

and no other individual or entity with a financial interest in the case that wishes to pursue the organization determination or coverage determination.

Comment: A commenter noted CMS proposed to permit the Part C and Part D IRE to dismiss a request when the independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation. The commenter requested CMS clarify who would be responsible for notification requirements when the IRE makes this determination.

Response: When the IRE makes a decision regarding a reconsideration, the IRE must comply with the notice requirements outlined in § 422.594 and § 423.602. This includes notifying the parties to the reconsideration of a dismissal.

Comment: A commenter noted that CMS proposed to add a new paragraph to § 422.590 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the MA organization's dismissal of a request for a reconsideration made under §§ 422.582(f) and 422.584(g). The commenter noted that the current process when a plan dismisses an appeal request is that the member has the right to go to the IRE to determine if the dismissal was correct. The commenter requested clarification on whether the proposed rule is stating the plan would send the case file to the IRE for all dismissals.

Response: This final rule codifies the current practice regarding dismissals, that the enrollee or other party to the reconsideration may file a request for review by the IRE of the plan's dismissal of a request for reconsideration. We believe that § 422.590(i), as proposed and finalized, is clear in establishing the regulatory authority for this request for IRE review in the MA context. We further clarify that this provision does not require MA plans to forward the case file to the IRE for all dismissals. MA plans and Part D plans must only forward the case file for a dismissal to the IRE when a proper party to the appeal requests IRE review of the dismissal under §§ 422.590(i) and 423.590(j). This is somewhat different than the process for Part C appeals under §§ 422.590 and 422.592, where the MA organization must gather and forward the

relevant information to the IRE for an automatic review by the IRE of reconsidered determinations (standard or expedited) that are not completely favorable to the enrollee.

Comment: A commenter noted that in some sections of the proposal, CMS indicated that it intends these dismissal determinations to be binding, but also notes the plan must include information on available appeal rights in the written notice of the dismissal. The commenter questioned if this would prohibit the requesting party(s) from resubmitting a claim with additional or new information. The commenter would like CMS to ensure as part of the process that a request could be resubmitted should new information come to light or was inadvertently not included in the initial request.

Response: CMS only intends that dismissals be binding to the extent outlined in these provisions. For example, § 422.568(j) provides for a dismissal of a request for an organization determination to be binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under § 422.568(i) of this section. So, as applied to this example, new or additional information could be submitted with a party's request for reconsideration of a dismissal (which would be requested under §§ 422.582 or 422.584) or considered as part of the MA organization finding good cause to vacate its dismissal of a request for an organization determination under the provisions at § 422.568(i). Note we have also added language to what we proposed at § 422.633(k) regarding vacating dismissals of integrated reconsiderations. The additional language aligns with the analogous provision for reconsiderations at §422.582(i).

Comment: A commenter questioned if CMS will modify the regulations concerning the withdrawal or dismissal of Part C and Part D determination requests, redetermination requests and IRE reconsiderations to better align with the regulations concerning limited English proficiency (LEP) communications.

Response: Entities that receive federal financial assistance, including Medicare Part C and D plans, must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency, in accordance with title VI of the Civil Rights Act of

1964 and section 1557 of the Affordable Care Act and implementing regulations (title VI and section 1557 respectively). Nothing in this final rule alters that requirement.

After consideration of the comments we received and for the reasons outlined in our responses and in the proposed rule, we are finalizing with modifications our proposed revisions to §§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600 to address withdrawals and dismissals by MA organizations, applicable integrated plans, and Part D plans. In addition to minor clarifications that are not substantive changes to our proposed regulations, we are also finalizing modifications compared to our proposals to clarify that plans are required to dismiss a request under the provisions of these final rules and to permit verbal withdrawal of requests for organization determinations, coverage determinations, reconsiderations, and redeterminations.

I. Methodology for Increasing Civil Money Penalties (CMPs) (§§ 422.760 and 423.760)

Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provide CMS with the ability to impose CMPs of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. The current regulations mirror the statute with respect to the amount of the penalty that CMS may impose for a per determination (contract level) penalty. Additionally, as specified in §§ 422.760(b)(2) and 423.760(b)(2) CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency. CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted

annually[68] for each affected enrollee or per determination, however CMS does not necessarily apply the maximum penalty amount authorized by the regulation.

CMS proposed to codify the methodology we would use to calculate the minimum penalty amounts that CMS would impose for certain types of program non-compliance by adding a new paragraph (b)(3) to §§ 422.760 and 423.760, and redesignating current paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

We proposed to update minimum penalty amounts no more often than every 3 years. CMS also proposed to increase the penalty amounts by including the increases that would have applied if CMS had multiplied the minimum penalty amounts by the cost-of-living multiplier released by the Office of Management and Budget (OMB)[69] each year during the preceding 3-year period. In addition, CMS proposed to track the yearly accrual of the penalty amounts and announce them on an annual basis.

Comment: We received one comment that supported our proposals. The commenter supported updating the minimum penalty amounts consistent with the three-year Part C and D organization audit cycle, and urged CMS to maintain the level of transparency afforded to the CMP methodology and updates.

Response*:* We thank the commenter for the support.

Comment: We also received one comment encouraging CMS to codify the process in which CMS notifies MA organizations and Part D sponsors of enforcement action referrals, including the opportunity to submit additional information before the final determination is made. Response: We appreciate the comment, but it is beyond the scope of the proposed

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[68] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 CFR 422.760(b), 423.760(b), and 460.46(a)(4) will be published annually in 45 CFR part 102. Pursuant to § 417.500(c), the amounts of civil money penalties that can be imposed for Medicare Cost Plans are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422. Section 1876 solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[69] Per OMB Memoranda M-19-04, *Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*, published December 14, 2018, the cost of-living adjustment multiplier for 2019 is 1.02522.

changes. However, we will consider it for future rulemaking. After consideration of the public comments received, we are finalizing this provision as proposed.

V. Codifying Existing Part C and D Program Policy

A. Plan Crosswalks for Medicare Advantage (MA) Organizations and Cost Plans (§§ 417.496 and 422.530)

We proposed to codify the current process and conditions under which MA organizations and 1876 cost plans can transfer their enrollees into the same plan from year to year when no other election has been made (this process is a "plan crosswalk"), as well as when MA organizations and cost plans can transfer their enrollees to other plans offered by the same MA organization or cost plan (this is a "crosswalk exception"). Our proposal was to define plan crosswalks, codify rules that protect a beneficiary's right to choose a plan, and specify the circumstances under which MA organizations and cost plans may transfer beneficiaries into another plan of the same type offered by the MA organization or, in the case of cost plans, transfer enrollees from that cost plan benefit package to another plan benefit package (PBP) under the same contract. In the proposed rule and this final rule, we generally use the terms "plan" and "PBP" interchangeably to refer to a specific plan offered under a contract. Specifically, the term PBP is used to describe the individual benefits packages that may be offered under a singular contract. Section 1851(c)(3)(B) of the Act provides for evergreen elections which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election, or the MA plan is discontinued or no longer serves the area in which the individual resides. In many cases, our crosswalk policy is a mechanism for operationalizing these evergreen elections.

Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. We proposed to codify existing policy regarding crosswalks and crosswalk exceptions using this authority and our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt standards and contract terms for MA organizations. In furtherance

of the beneficiary's right to choose and implementing evergreen elections, we proposed to codify existing policy in new regulations at § 417.496 and § 422.530 to define plan crosswalks, implement rules that protect a beneficiary's right to choose a plan, and describe allowable circumstances under which MA organizations may transfer beneficiaries from one of its MA plans into another of its MA plans or a cost contract may transfer beneficiaries from one of its plans into another of its cost plans. With respect to cost plans, we proposed to codify existing enrollment policy related to the transfer of enrollees from one of an entity's PBPs to another PBP, under the authority of section 1876(i)(3)(D) of the Act, which requires that cost contracts shall contain such other terms and conditions, not inconsistent with the statute, as the Secretary may find necessary and appropriate. Our proposal and this final rule do not include rules for deeming enrollment from a cost plan to an MA plan under sections 1876(h)(5)(C) and 1851(c)(4) of the Act because the statute does not permit deeming of enrollees from cost plans to MA plans beyond contract year 2018.

We also proposed, at § 422.530(d), to codify the procedures that an MA organization must follow when submitting a crosswalk or a crosswalk exception request. An MA organization must submit all allowable crosswalks in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS. Through the bid submission process, the MA organization may indicate if a crosswalk exception request is needed at that time, but the MA organization must request a crosswalk exception later through the crosswalk exception functionality in HPMS by the deadline announced by CMS. CMS verifies the exception request and notifies the requesting MA organization of the approval or denial of the request after the crosswalk exception deadline has expired. These exceptions must be submitted by the MA organization to ensure that plan benefit package (PBP) enrollment is allocated appropriately.

CMS has developed extensive guidance addressing the transfer of enrollees from one PBP offered by an organization to another PBP offered by that organization under the same

contract.[70] The guidance, applicable to MA organizations and cost plans, was developed in light of the ability of MA organizations and cost plans to revise their benefit offerings and PBPs from year to year. The transfer of enrollees from one PBP to another under these circumstances serves to facilitate evergreen elections. MA organizations frequently make business decisions resulting in changes to and in their MA plans offered for enrollment in the following contract year. Each year, through the bid process for plan design and an application process for service area changes, MA organizations submit changes in coverage and cost sharing design for their MA plans. In addition, MA organizations have the ability to terminate existing plans and apply to offer new plans. While cost plan organizations may not offer new cost plans, they also may make changes in their benefit and cost sharing design and seek service area changes through an annual process. CMS has issued annual sub-regulatory guidance related to changes of this type for MA and cost plans to address how MA organizations and cost plans may transition enrollees from a plan that is terminating or changing its service area to another plan offered by the same organization. These transitions are useful to preserve beneficiary enrollment and are subject to a number of beneficiary protections. We proposed to codify existing crosswalk policy to clearly identify the basic rules for plan crosswalks, including the parameters for allowable crosswalks, and formalize CMS's crosswalk exception review process. Crosswalk exceptions are specific circumstances where a crosswalk is not automatically authorized under our policies but CMS may permit MA organizations and cost plans to transfer beneficiaries into another plan of the same type offered by the MA organization or cost plan after a review, provided that certain requirements are met. The crosswalk exceptions process, as currently conducted and as proposed, allows CMS to review and validate the existence of an exception and then manually effectuate the transaction in our system. Crosswalk exceptions are not part of the standard, annual PBP renewal process. We

[70] Chapter 16b of the Medicare Managed Care Manual and Process for Requesting an HPMS Crosswalk Exception for Contract Year (CY) 2020 (released annually).

proposed to codify these new regulations at §§ 417.496 and 422.530 to govern, respectively, cost plans and MA organizations.

We proposed, at §§ 417.496(a)(1) and 422.530(a)(1), to define a plan crosswalk as the movement of enrollees from one PBP to another PBP under the same contract between the MA or cost organization and CMS. MA and cost organizations complete these crosswalk transactions annually as part of the renewal process. Unlike MA plans, however, cost plans do not include different plan types such as PPOs, PFFS, and special needs plans, therefore proposed § 417.496(a)(2) did not specify that crosswalks from one plan type to another are prohibited while proposed § 422.530(a)(2) did.

In proposed § 422.530(a)(5), we defined the types of MA plans that are "different plan types" for purposes of crosswalk policy: health maintenance organizations, provider-sponsored organizations, and regional and local preferred provider organizations coordinated care plans are different plan types, even though they are all coordinated care plans. Additionally, we noted that the segmented plans are not a "type" of plan in MA and that crosswalks are permitted between segmented and non-segmented plans. We did not include in the proposed cost plan crosswalk regulation provisions about contract transactions related to plan types and policies such as segmentation and continuation because they are specific to MA contract transactions. The majority of crosswalks involve moving enrollees from one contract year plan to the corresponding plan for the following contract year. Therefore, under our current policy and the proposal, enrollees are not required to make an enrollment election to remain enrolled in their chosen plan. In § 417.496(a)(2)(i), we proposed to codify the general rule that crosswalks are prohibited between different cost contracts, and in § 417.496(a)(2)(ii), we proposed to codify that crosswalks are prohibited between different cost plan IDs under a cost contract unless the crosswalk qualifies for an exception to this requirement. In § 417.496(c)(1)(i) and (ii) we proposed to codify the exception that cost contracts terminating PBPs with optional supplemental benefits may transfer enrollees to another PBP with or without optional benefits under the same

cost contract as long as enrollees who have Part A and B benefits only are not transferred to a PBP that includes Part D. In § 417.496(c)(1)(iii)(A), (B), and (C), we proposed to codify the rule that an enrollee in a terminating PBP that includes Part D may only be moved to a PBP that does not include Part D if the enrollee is notified in writing that she/he is losing Part D coverage, the options for obtaining Part D, and the implications of not getting Part D through some other means. In § 422.530(a)(2), we proposed to codify the general rule that crosswalks are prohibited between different MA contracts or different plan types (for example, HMO to PPO), which means that crosswalks are only permitted between plans of the same type under the same contract. However, proposed § 422.530(c) specified the limited circumstances in which CMS would allow a crosswalk transaction that does not comply with this general prohibition on crosswalks to different contracts. We included in proposed § 422.530(a)(2) a reference to these "exceptions" permitted under paragraph (c). We explained that these exceptions in § 422.530(c) apply to MA plans only because they pertain to MA policies; therefore, we did not propose similar regulation text in § 417.496.

As most plan crosswalks are related to contract renewals and non-renewals, we proposed a general rule at § 422.530(a)(3) that would require MA organizations to comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to be eligible to complete plan crosswalks. In § 417.496(a)(3), we proposed that cost plan entities must comply with the renewal and non-renewals rule per §§ 417.490 and 417.492, in order to be eligible to complete plan crosswalks. In § 422.530(a)(4), we proposed that enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP as part of a crosswalk.

In §§ 422.530(b) and 417.496(b), we proposed to codify the existing crosswalk policy by specifying the circumstances under which a crosswalk is permitted so that an MA organization or cost plan may move enrollees into, respectively, another MA plan or cost plan. For MA plans, in paragraph (b)(1), we proposed permissible crosswalks for all plan types and in paragraph (b)(2),

we proposed crosswalks that are permissible only for MA special needs plans (SNPs). We reminded readers that the MA plan types are identified in § 422.4; therefore, we specified in proposed § 422.530(a)(5) that the different types of coordinated care plans are considered different "plan types" for purposes of crosswalking policy. For cost plans, in proposed paragraph (b), we addressed permissible crosswalks for cost plans. Each of these proposals was consistent with current policy.

1. Cost Plans and All MA Plan Types

a. Renewal Plan

Under existing program rules, an MA or cost organization may continue to offer, that is renew, a current PBP that retains all of the same service area for the following year; the renewing plan must retain the same PBP ID number as in the previous contract year. We proposed to codify moving the enrollees in the existing PBP to the PBP with the same ID number for the following year as a permissible crosswalk in paragraph (b)(1)(i) for MA plans and § 417.496(b)(1) for cost plans. Under the proposal, as with current policy, current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will transition all enrollees from the current PBP to the new PBP with the same PBP ID number for the following year. New enrollees must complete enrollment requests, and the MA or cost organization will submit enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 current MA and cost enrollees of a renewed PBP, respectively, must receive an Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

b. Consolidated Renewal Plan

Under existing program rules, MA and cost organizations may combine two or more PBPs offered under the same contract in the current contract year into a single renewal plan, as a plan consolidation. We explained that when the consolidation includes two or more complete

PBPs being combined and no PBP being split among more than one PBP in the next contract year, the MA or cost organization is permitted to transition all enrollees in the combined plans under one PBP under that contract, with the same benefits in the following contract year; the resulting PBP must have the plan ID of one of the consolidated plans. We proposed to codify this as a permissible crosswalk in §§ 417.496(b)(2) and 422.530(b)(1)(ii) and explained that under the proposal (as with current policy), current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees. The renewal PBP ID is used to transition current enrollees of the plans being consolidated into the designated renewal plan. In operationalizing this crosswalk, the MA or cost organization may need to submit updated data to CMS for the enrollees affected by the consolidation. New enrollees in the consolidated renewal plan must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees in the consolidated renewal plan.

c. Renewal Plan with a Service Area Expansion (SAE)

Under existing program rules, an MA or cost organization may continue to offer the same cost plan or local MA plan but expand the service area to include one or more additional counties for the following contract year. We explained that to expand the service area of its plan(s), an MA or cost organization must submit a service area expansion (SAE) application to CMS for review and approval; CMS treats service area expansions as applications subject to the rules in part 422, subpart K, and § 417.402. Under our current policy an MA or cost organization renewing a plan with a SAE must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in that plan the following contract year; current enrollees of a PBP that is renewed with a SAE are not required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees but can

transition all enrollees using a crosswalk from the current PBP to the new PBP with the same PBP ID number for the following year. We proposed to codify this as a permissible crosswalk in § 422.530(b)(1)(iii) for MA plans and § 417.496(b)(3) for cost plans. New enrollees must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees of a renewed PBP with a SAE.

d. Renewal Plan with a Service Area Reduction

Under existing program rules, an MA organization offering a local MA plan may reduce the service area of a current contract year PBP; similarly, a cost organization may reduce the service area of a cost plan. We explained that this service area reduction (SAR) means that enrollees who were in the part of the service area being reduced will generally not be eligible to remain in the plan because of the residence requirement in §§ 417.422(b), 422.50(a)(3), and 422.54. We addressed crosswalks that may occur in connection with a service area reduction in proposed §§ 422.530(b)(1)(iv) and 417.496(b)(4). Under our proposal (as in current practice), when there is a service area reduction for a plan, the MA organization or cost plan may only crosswalk the enrollees who reside in the remaining service area to the plan in the following contract year that links to a current contract year plan but only retains a portion of the prior service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area. MA organizations may have different options available to them in terms of notices and the ability to offer a continuation of enrollment under § 422.74(b)(3)(ii) depending on the other MA plans in the service area at the time of the service area reduction. We included regulation text in proposed § 422.530(b)(1)(iv)(A) and (B) to address the different scenarios.

We proposed in § 422.530(b)(1)(iv)(C), that enrollees that are no longer in the service area of the MA or cost plan will be disenrolled at the end of the contract year and will need to

elect another plan (or default to original Medicare). The MA or cost organization must submit disenrollment transactions to CMS for these enrollees. In addition, the MA or cost plan organization must send a Medigap guaranteed issue rights to the affected enrollees and a non-renewal notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP). We proposed to codify at § 422.530(b)(1)(iv)(D) specific rules about what information may be provided by the MA organization about its other MA plan options in the area that will no longer be part of the service area of the continued plan. Per the marketing and communication regulations, at §§ 422.2263(a) and 423.2263(a) and discussed elsewhere in this final rule, marketing information about other MA plan options offered by the MA organization for the prospective plan year can begin October 1 of each year for the following contract year.

2. Special Needs Plans (SNPs)

Under our current crosswalk policies, MA Special Needs Plans (SNPs) follow the general rules, which we proposed to codify in § 422.530(b)(1), and are permitted additional flexibility for crosswalks in specific situations. We proposed regulation text to identify the additional crosswalks permitted for SNPs in § 422.530(b)(2), which vary based on the type of SNP. In the proposed rule, we explained that MA organizations may not crosswalk enrollees from one SNP type to a different SNP type, as that would constitute crosswalking into a different type of plan, which is prohibited by § 422.530(a)(2). We clarify here as well that the rules in paragraph (a) all apply to the crosswalk authority for SNPs described in paragraph (b)(2) just as the rules in paragraph (a) apply to the crosswalk authority in paragraph (b)(1).

a. Chronic Condition SNPs (C-SNPs)

We proposed to codify four permissible crosswalks specific to C-SNPs at § 422.530(b)(2)(i)(A) through (D). C-SNPs serve and are limited to enrolling special needs individuals who have a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan. The MA organization offering the C-SNP may target one

or more specific severe or disabling chronic conditions. When a C-SNP targets more than one severe or disabling chronic condition, we refer to that as a "grouping" and we have addressed groupings in guidance in Chapter 16b of the Medicare Managed Care Manual. We proposed that these permissible crosswalks reflect the limitations on eligibility for C-SNPs, as different C-SNPs serve different populations depending on the chronic condition(s) targeted for enrollment restriction.

• Renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

• Non-renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

- Renewing C-SNP with a grouping that is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from the grouping.

• Non-renewing C-SNP in a grouping that is transitioning eligible enrollees into a different grouping C-SNP if the new grouping contains at least one condition that the prior plan contained.

b. Institutional-SNPs

We proposed to codify five permissible crosswalks specific to I-SNPs at § 422.530(b)(2)(iii)(A) through (E). I-SNPs are limited to enrolling individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in§ 422.2. I-SNPs may limit their enrollment to either institutionalized or institutionalized-equivalent individuals or may enroll both categories of individuals. These permissible crosswalks reflect the enrollment limitations on I-SNPs.

• Renewing Institutional SNP that transitions enrollees to an Institutional/ Institutional Equivalent SNP.

• Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/ Institutional Equivalent SNP.

• Renewing Institutional/ Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

• Renewing Institutional/ Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

• Non-renewing Institutional/ Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/ Institutional Equivalent SNP.

c. Dual Eligible-SNPs (D-SNPs)

We did not propose to codify any permissible crosswalks specific to D-SNPs, which is consistent with our current crosswalk policy (which does not authorize additional crosswalk scenarios for D-SNPs outside of the crosswalk exceptions).

d. Exceptions

In some instances, crosswalk actions must be manually reviewed and entered by CMS staff. We call these *crosswalk exceptions*. We proposed to codify at § 422.530(c) when CMS will approve a request for a crosswalk exception and permit crosswalks in situations that are not specified in § 422.530(b). These exceptions address certain unusual circumstances involving specific types of plans or contract activities. Under our proposal, only an exception specified in § 422.530(c) would be approved and recognized as an additional circumstance when a crosswalk is permitted. We proposed to allow the following exceptions to the limits on the crosswalk process:

• When a non-network or partial network based private fee-for-service (PFFS) plan is transitioning to either a partial network or a full network PFFS plan, we would permit a crosswalk when CMS determines it is in the interest of beneficiaries. CMS will consider whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. We anticipate that granting these exceptions would be extremely rare since in the great majority of instances enrollees have

choices of multiple MA plans or Original Medicare and are able to exercise their choice. We specifically proposed to restrict crosswalks between these network and non-network PFFS plans because the way enrollees will access health care services is significantly different in each of these plans. Section 1852(d)(5) of the Act establishes that in areas that are determined to be "network areas" PFFS plans can only operate by having a network of providers that meets CMS current network adequacy standards. The network based PFFS plan functions very much like a MA PPO plan in that there is a network of contracted providers through which enrollees can obtain Medicare covered services. In addition, an enrollee in a network based PFFS plan has the option of also going out-of-network for plan covered services though their cost sharing may be higher. However, in areas of the country that have determined to be non-network areas with respect to PFFS plans, the PFFS plan can operate without a network and enrollees must seek care from any willing provider under the non-network PFFS plan's terms and conditions of payment. Because these two types of PFFS plans function very differently for enrollees obtaining covered health care services, we do not believe crosswalks should be generally permitted between these two types of PFFS plans.

• When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts consolidated under one surviving contract, the enrollees from the consolidating plans may be moved to an MA plan under the surviving plan. As a result of the consolidation of contracts, enrollees from at least one of the PBPs are transitioned to another contract; therefore, CMS limits approval of these crosswalks to an exception because of the movement across different contracts. As part of reviewing a request for this crosswalk exception, CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).

• When a renewing D-SNP in a multi-state service area is reducing its service area to accommodate a state contract in part of the service area, we would permit enrollees who are no longer in the service area to be moved into one or more new or renewing D-SNPs for which they

are eligible, when CMS determines it is necessary to accommodate changes to D-SNP state contracts. We proposed to codify this crosswalk exception at § 422.530(c)(3).

• When an MA organization renews a D-SNP for the upcoming contract year with changes in the D-SNP eligibility criteria, has another available new or renewing D-SNP for the upcoming contract year, and the two D-SNPs are offered to different populations, we would permit a crosswalk exception if it is in the best interest to current enrollees who are no longer eligible for their non-renewing D-SNP. We proposed to codify this crosswalk exception at § 422.530(c)(4). An MA organization may change – or as part of state contracting, may be required to change – a D-SNP's eligibility criteria for the upcoming contract year. As a result, some current enrollees may no longer be eligible for their current D-SNP. However, the MA organization may have a new or renewing D-SNP in the same service area with eligibility requirements that can accommodate the enrollees who are no longer eligible for their current D-SNP.

• When a renewing C-SNP with a grouping of multiple conditions is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from that grouping. This crosswalk exception, which we proposed to codify at § 422.530(c)(5), differs from the allowable crosswalk in proposed § 422.530(b)(2)(i)(B) because it is a renewing C-SNP and not a non-renewing C-SNP. A crosswalk exception is required in order for CMS to identify which enrollees are moving from the renewing plan C-SNP to the other C-SNP. In a non-renewing C-SNP, all enrollees would be crosswalked to another plan or disenrolled.

In the proposed rule, CMS explained that the crosswalk policies we proposed to codify are designed to protect the rights of enrollees to make a choice about the plan from which they wish to receive Medicare benefits while facilitating how section 1851(c)(3)(B) of the Act requires evergreen elections. We proposed to codify policies and standards that CMS has implemented that allow MA and Cost organizations the flexibility to make business decisions about the benefit and cost sharing design of a plan while preserving the rights of beneficiaries to

make informed choices about their health care coverage. We summarize the comments we received on these crosswalk proposals and our responses.

Comment: CMS received a comment specific to the crosswalk exceptions process for cost plans. The commenter expressed concern with CMS having an exception permitting cost organizations to move enrollees from one of its plans with Part D to a plan that does not have Part D. The commenter stated that enrollees might not be aware of the implications of losing Part D and, as a result, CMS should require that enrollees actively "opt out" of Part D before being enrolled by the cost organization into one of its non-Part D plans. The commenter acknowledged that we proposed that the cost organization be required to notify enrollees of the implications of losing Part D but expressed concern that this information could become lost in the barrage of advertising and other materials mailed during the annual enrollment period.

Response: We believe that the notice requirements proposed and finalized at § 417.496(c)(1)(iii) offer robust protections for enrollees. Cost enrollees with Part D may be crosswalked to a plan without Part D because, unlike MA plans, Part D can only be an optional supplemental benefit for cost enrollees. In addition to specific information on plan benefits and costs for the new plan, affected enrollees will receive information from the cost organization on the implications of losing creditable Part D coverage and options for acquiring Part D coverage. In addition, the enrollee will have the annual coordinated election period to choose another Part D plan or to elect coverage in another Medicare health plan that does offer Part D coverage. We also believe that the provision as proposed strikes the proper balance between protections for enrollees and flexibility for cost organizations. CMS is therefore finalizing § 417.496.

Comment: CMS received comments asking for a waiver of the requirement to provide an Annual Notice of Change (ANOC) document to enrollees who are crosswalked between SNP plans under the same legal entity if there are no substantive changes in premiums, benefits, and cost-sharing as a result of the transition.

Response: Under § 422.111, MA organizations are required to disclose key changes to coverage to all enrollees annually. This crosswalk regulation was not proposed to, and as finalized does not, supersede or circumvent those disclosure requirements. The ANOC requires any and all changes to premiums, benefits, and cost-sharing to be disclosed in the ANOC, not just substantive changes. In addition, the ANOC requires these plans to make it clear that if a beneficiary doesn't make a different choice, they will be automatically enrolled in the new plan. This helps preserve the beneficiary's right to make an informed choice about their health care coverage.

Comment: Commenters are seeking additional options to comply with the D-SNP integration requirements set forth in the BBA of 2018 and the implementing regulations. Several commenters suggested allowing D-SNP crosswalk exceptions to permit a non-renewing D-SNP plan benefit package (PBP) of one legal entity to crosswalk into a new or renewing D-SNP PBP of another legal entity within the same parent organization in cases where it would facilitate integration for dually eligible individuals in Medicare and Medicaid.

Response: We thank commenters for their suggestion. In our recent experience, contracting processes between D-SNPs and states to comply with provisions of the BBA of 2018 are raising new questions and challenges. In some cases, the current way a parent organization structures its MA contracts using different subsidiaries (so that the MA organizations on various contracts are different legal entities) may raise an impediment to achieving higher levels of integration between Medicare and Medicaid. Moving enrollees from one PBP to another PBP operated by the same parent organization but under a different legal entity, in some cases, could result in better experiences and outcomes for enrollees but may not always be permitted as a crosswalk under our proposal.

Under current rules, and without a crosswalk exception, there are two mechanisms for moving D-SNP members into another D-SNP operated by another MA organization under the same parent organization: (1) consolidating contracts consistent with the change of ownership

regulations (§§ 422.550 through 422.553), then crosswalking between plans in the next year; or (2) if approved by CMS, under the passive enrollment provisions at § 422.60(g). These mechanisms may be appropriate in some instances, but they may be more burdensome than we believe necessary in some types of within-parent-organization scenarios posed by commenters. The passive enrollment provision is also more narrowly targeted to enrollees already in an integrated D-SNP who would move to a fully integrated or highly integrated D-SNP, circumstances that would be most applicable when state Medicaid managed care contracting results in disruption of a current integrated care arrangement.

We proposed to permit two crosswalk exceptions for D-SNPs specifically at § 422.530(c)(3) and (c)(4). The first would allow an MA organization renewing a D-SNP in a multi-state service area that is reducing its service area to accommodate a state contract in part of the service area to crosswalk enrollees who are no longer in the service area to one or more new or renewing D-SNPs for which they are eligible, when CMS determines it is necessary to accommodate changes to D-SNP state contracts. The second would apply for an MA organization renewing a D-SNP for the upcoming contract year with changes in the D-SNP eligibility criteria, but which has another available new or renewing D-SNP for the upcoming contract year, where the two D-SNPs are offered to different populations. In this scenario, we proposed to permit a crosswalk exception if it is in the best interest to current enrollees who are no longer eligible for their D-SNP to allow such a crosswalk exception.

We agree with commenters that – where necessary to accommodate changes to D-SNP state contracts – we should permit crosswalk exceptions in additional scenarios. We are finalizing § 422.530(c)(3) in the final rule with two significant changes compared to the proposed rule. First, we are finalizing additional language applying this exception to multi-state regional PPOs (RPPOs). Our original proposal focused on service area reductions by multi-state D-SNPs. However, multi-state RPPOs cannot eliminate states from their service areas while remaining RPPOs. As finalized, § 422.530(c)(3) also allows a non-renewing D-SNP that is a MA

regional plan (an RPPO) to crosswalk enrollees to D-SNPs in state-specific local PPOs. Second, we are finalizing additional language to allow crosswalking of members across D-SNPs within the same parent organization but across legal entities in these scenarios. This crosswalk exception in § 422.530(c)(3) only applies for D-SNPs with multi-state service areas, and we believe § 422.530(c)(3) as finalized with these changes will create additional opportunities to comply with state D-SNP contracting while promoting continuity of care for enrollees. We are declining, at this time, to extend this crosswalk exception to D-SNPs without multi-state service areas to allow us additional opportunity to assess the potential impacts of such a change. The D-SNP crosswalk exception we proposed and are finalizing at § 422.530(c)(4) does not require that the D-SNP service areas include multiple states and is not limited to accommodating changes to the contracts between the state(s) and the D-SNP under § 422.107; this other crosswalk exception addresses changes in the eligibility criteria for the current year D-SNP and permits moving enrollees to another D-SNP offered by the same MA organization where CMS determines it is the best interests of the enrollees to move to the other D-SNP for the new contract year in order to promote access to and continuity of care for the enrollees whose enrollment would be terminated from the D-SNP based on the change in eligibility criteria. We are declining, at this time, to extend this crosswalk exception at § 422.530(c)(4) to D-SNPs offered by different MA organizations, even if the parent organization is the same, to allow us additional opportunity to assess the potential impacts of such a change.

We will consider other potential crosswalk exceptions for future rulemaking.

After consideration of the public comments we received and for the reasons outlined in the responses to comments and the proposed rule, we are finalizing our proposal with the following modifications:

- Section 422.530(c)(1) is being finalized with additional text from the preamble of the proposed rule (85 FR 9091) to identify the factors considered by CMS in making a determination that moving enrollees from a non-network or partial network PFFS plan to a partial or full-

network PFFS plan is in the interest of beneficiaries. The factors CMS will take into consideration are whether enrollees would be better served by being crosswalked to the new PFFS plan. Another consideration is if there are no other MA plans available where the enrollee resides (including whether there are a number of potentially more suitable MA plans available for the enrollee to select) and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. A PFFS plan requesting a crosswalk of enrollees from a non-network PFFS plan to a partial or full-network PFFS plan would need to include in their exception request an explanation of why the crosswalk would be in the best interest of the beneficiary (or beneficiaries) rather than the alternative of the enrollee(s) making an selection among available MA plans or Original Medicare during the Annual Election Period. This section also finalizes the requirement that CMS will not permit crosswalks from network based PFFS plans to non-network or partial network PFFS plans. As discussed in the proposed rule, CMS is finalizing this requirement because network based PFFS plans function very much like an MA PPO plan. In consequence, an enrollee in a network based PFFS plan crosswalked to a non-network or partial network PFFS plan would no longer have assured access to a network of contracted providers. Such a change in how their plan functions would be significant and potentially problematic for the enrollee in accessing their health care services.

• Section 422.530(c)(2) is being finalized with a slight revision to clarify that MA contracts, rather than MA plans, are consolidated. When MA contracts under two different MA organizations that share a parent organization are consolidated, the MA plans under the different contracts are then offered under the surviving MA contract. Some of the MA plans may also be consolidated under the surviving MA contract. The crosswalk exception permits the enrollees from the consolidated contracts to be crosswalked to an MA plan under the surviving contract.

- Section 422.530(c)(3) is being finalized as proposed to address multi-state D-SNPs and with additional text to address a crosswalk exception for non-renewing D-SNPs in multi-state RPPOs. In situations involving both types of D-SNPs, a crosswalk

exception may be permitted in cases CMS determines it is necessary to accommodate changes to state contracts, as discussed in more detail in the response to the public comment. Section 422.530(c)(3) is also being finalized with additional text to clarify that the crosswalk exception permits moving enrollees to a different contract,

- Section 422.530(c)(4) is being finalized with additional text to clarify that the receiving D-SNP must be offered by the same MA organization and to specify that CMS would approve the crosswalk exception if the enrollees are eligible for the receiving D-SNP and CMS determines the crosswalk exception would be in the best interests of enrollees in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception.

- The crosswalk proposed at § 422.530(b)(2)(C) to permit a renewing C-SNP with a grouping that is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from that grouping is not being finalized because it was duplicative of proposed § 422.530(c)(5), which is being finalized. Under our current policy, an exception is not automatically granted in this situation. We believe that codifying our current policy on this point is appropriate. What was proposed at § 422.530(b)(2)(D) is being finalized as § 422.530(b)(2)(C) instead.

- Finally, we are finalizing the regulation text at § 417.496(c)(1) and introductory text at § 422.530(c) using "may permit" instead of "permits" to clarify that CMS approval is not automatic for the crosswalk exceptions.

As finalized, § 422.530 also contains several non-substantive grammatical and technical changes to improve the clarity and readability of the regulation text.

B. Medicare Advantage (MA) Change of Ownership Limited to the Medicare Book of Business (§§ 422.550 and 423.551)

Section 1857 of the Act requires each MA organization to have a contract with CMS in order to offer an MA plan. Section 1857(e)(1) of the Act authorizes the adoption of additional

contract terms that are consistent with the statute and that the Secretary finds are necessary and appropriate. Consistent with this authority, at the beginning of the Part C program we implemented contracting regulations in § 422.550 which provide for the novation of an MA contract in the event of a change of ownership involving an MA organization. (63 FR 35106) Under the regulations, codified at §§ 422.550 through 422.553, the execution of a novation agreement is required when an MA organization is acquired or when it wants to transfer its ownership to a different entity. When an MA organization is no longer able or willing to participate in the MA program, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to enrolled beneficiaries. In this instance, CMS has an interest in agreeing to a novation of the existing MA contract because it promotes the efficient and effective administration of the MA program.

We proposed to revise § 422.550 by adding a new paragraph at § 422.550(f) to restrict the situations in which CMS will agree to an MA contract novation to those transfers involving the selling of the organization's entire line of MA business, which would include all MA contracts held by the legal entity that is identified as the MA organization. It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights. We explained that the change codifies existing policy and also create more consistency in regulations between the Part D program, which has an explicit regulation requiring the sale of the entire book of Part D business at § 423.551(g), and the MA program.

In the proposed rule, we explained that this policy has not been applied in cases where contracts are transferred among subsidiaries of the same parent organization and we do not wish

to interfere with an MA organization's (or parent organization's) ability to decide its corporate structure or contractual arrangements with its subsidiaries. Therefore, we also proposed, at § 422.550(f)(1), an exception to the proposed limit for changes of ownership to only when the entire MA book of business is being transferred; that exception would be when the sale or transfer is of a full contract between wholly owned subsidiaries of the same parent organization.

We proposed to codify explicitly in § 422.550(f)(2) that CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one MA contract if the organization holds more than one MA contract. We stated that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights as our primary rationale for this proposal.

We thank commenters for their input to help inform our final rule on changes of ownership. We received the following comments on this proposal, and our responses follow:

Comment: Some commenters were supportive of CMS's proposal and agreed that allowing a sale or transfer that consists solely of the sale or transfer of a cohort of beneficiaries/contracts, if the organization holds more than one MA contract, can have a negative impact on beneficiary election rights. Additionally, we received support on the exception to allow the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization.

Response: We thank commenters for their support of our proposal.

Comment: A commenter suggested that CMS's proposal would remove a viable option for an organization to transfer a contract with minimal disruption to enrollees because the enrollee would move with the contract and the move would be invisible to the enrollee. They explained that this limitation would require an organization to retain a contract that is not working and force them to exit the MA market entirely in order to close an underperforming contract.

Response: Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. Additionally, section 1851(c)(3)(B)(ii) of the Act provides for evergreen elections, which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election or the MA plan is discontinued or no longer serves the area in which the individual resides. Both of these statutes protect an enrollee's right to choose and remain in an MA plan of their choosing. We believe that allowing the sale or transfer of contracts, without the entire line of business, does not support the enrollee's right to choose their MA plan under the statute because a plan offered and administered by a specific MA organization is necessarily different than a plan, even with the same benefits coverage and cost sharing, offered and administered by a different organization. A different parent organization is likely to have different administrative policies and processes, such as appeals processing, medical necessity policies, or customer service functions, which an enrollee should be able to consider before electing to enroll in a plan. An individual that has elected coverage in a plan offered by one entity is necessarily choosing not to be in a plan offered by a different entity; the sale of a single contract frustrates those choices. We distinguish this from the sale or transfer of the entire line of business to another MA organization, where the seller/transferor is choosing to leave the market entirely and the buyer/transferee is taking on all responsibilities and obligations to continue providing benefits to all enrollees without interruption. Also, we disagree that this limitation would require a plan to retain a contract that is not working and force them to exit the MA market entirely in order to close an underperforming contract. MA organizations retain the right to non-renew a contract for any reason, provided it meets the timeframes for doing so at § 422.506, and may continue to operate other existing MA contracts without interruption.

Comment: A commenter requested that CMS clarify whether the divestiture of an MA organization's business would allow the blending of contracts by virtue of a novation.

Response: By "blending" we understand the commenter to be referring to combination of transferring a contract to a new MA organization and consolidating the contracts at the same time. The divestiture of an MA organization's entire line of business does not allow those transferred contracts to be consolidated with the acquiring MA organization's existing contracts in the same year. In other words, the plans in the acquired contract must continue to operate under their given contract number. After the acquisition is complete and during the next bidding cycle, the MA organization may follow crosswalk rules finalized at § 422.530 in order to consolidate contracts into a single contract.

Comment: Two commenters recommended that CMS allow flexibilities to transfer or sell plans or contracts under certain, additional conditions through specific exceptions to the "entire line of business" rule. One commenter recommended that we create an exception based on certain geographies or markets. Another commenter recommended an exception based on special circumstances, such as one involving the sale of an I-SNP. The commenter suggested that the sale of an I-SNP would benefit the Medicare program and beneficiaries because the acquiring MA organization could better serve that population and would likely be a better solution to maintain appropriate coverage for the impacted beneficiaries over terminating the contract.

Response: It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line of business, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights, particularly where an exception is based on a decision that a specific plan or MA organization is "better for" enrollees. The same policy is in place in the Part D program, in § 423.551(g). We do not believe that

allowing an exception based on "special circumstances", either because of a product type (for example, I-SNP) or characteristics of a region or marketplace, outweighs the importance of upholding an enrollee's right to elect a plan of their choosing. Additionally, commenters did not provide specific information about which markets or geographic regions would benefit from this type of exception and why an exception for specific areas is necessary for us to evaluate in more detail. We may monitor issues like this and consider specific exceptions to this policy in future rulemaking.

Comment: A commenter recommended that we consider special circumstances permitting an MA organization to transfer one PBP to another legal entity within the same parent organization in cases where it would facilitate D-SNP integration. The commenter explained that an MA organization may need to shift a D-SNP PBP to an H-contract affiliated with a different legal entity to meet federal requirements that FIDE plans be on the same legal entity as the corresponding Medicaid product.

Response: We do not agree that adding explicit regulatory text to permit an organization to transfer one PBP in a contract to another legal entity (even if limited to transfers within the same parent organization) in cases where it would facilitate D-SNP integration is necessary. The regulatory text, as proposed and finalized, permits the sale or transfer of a single contract (that is not the full book of business) where both MA organizations (the seller and the buyer) are wholly owned subsidiaries of the same parent organization, regardless of the plan types under the contract. Additionally, MA organizations will be able to use crosswalk exceptions discussed in section V.A of this final rule to facilitate D-SNP integration with § 422.107. As we discuss in Section V.A of this final rule, we are permitting, at § 422.530(c)(3), an MA organization to crosswalk enrollees from one PBP to a PBP of another legal entity within the same parent organization in certain cases where it is necessary to accommodate changes to the D-SNP state contracts required under § 422.107. We believe these crosswalk exceptions, as finalized, will

provide MA organizations with any additional flexibility needed to accommodate D-SNP integration.

Comment: One commenter recommended that we consider special circumstances allowing an MA organization to buy or sell a single PBP when the intent is to promote integration for dual eligible beneficiaries. The commenter explained that the ability to sell a D-SNP PBP to an existing, incoming, or re-procured Medicaid organization will prevent disruption that otherwise would occur when a D-SNP must exit a market (unless authority for Medicare passive enrollment is expanded).

Response: We do not agree that adding explicit regulation text to permit an organization to buy or sell one PBP to another legal entity to facilitate D-SNP integration is necessary. The regulation text, as proposed and finalized, permits the sale or transfer of a single contract (that is not the full book of business) where both MA organizations (the seller and the buyer) are wholly owned subsidiaries of the same parent organization, regardless of the plan types under the contract. In accordance with § 422.552(a)(3)(iii), which has been in place for several years, the successor organization must meet the requirements to qualify as an MA organization under part 422, subpart K; this means that all of the requirements to offer a SNP must also be met if the contract includes PBPs that are SNPs. We do not believe carving out a specific PBP from a contract, even if that PBP is a D-SNP, to sell the PBP would serve MA program purposes and goals. In addition, we do not believe that an expansion of the passive enrollment authority for the MA program is within the scope of this rulemaking.

Comment: One commenter recommended that the last part of the sentence in § 422.550(f)(2) – "or one contract if the organization holds more than one MA contract" – be removed because it contradicts § 422.550(f)(1) which explicitly allows an exception for one contract when it is owned within the same parent organization. They also recommended that the corresponding language in the Part D regulation at § 423.551(g)(2)) be revised.

Response: We agree with the commenter and believe the removal of "or one contract if the organization holds more than one MA contract" would reduce potential confusion. We also agree that the same change should be made to the Part D regulation at § 423.551(g)(2), since the proposed language at § 422.550(f)(2) was meant to mirror the language in § 423.551(g)(2). Therefore, we are modifying the regulation at § 422.550(f)(2) and § 423.551(g)(2) to remove "or one contract if the organization holds more than one MA contract." We emphasize that the prohibition on transfers or sales of single contracts, is prohibited under the first sentence of § 422.550(f)(1) and 423.551(g)(1): CMS will not recognize the sale of anything less than an MA organization or PDP sponsor's book of business except for the limited situation where the sale or transfer of a full contract is between wholly owned subsidiaries of the same parent organization. Further, CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the comments, we are finalizing the proposed changes to § 422.550(f) without the phrase "or one contract if the organization holds more than one MA contract" in § 422.522(f)(2). We are also finalizing a change to § 423.551(g)(2) to remove "or one contract if the organization holds more than one MA contract."

C. Supplemental Benefit Requirements (§§ 422.100)

CMS has released guidance on supplemental benefits several times since April 2, 2018, including the 2019 Call Letter[71] and a subsequent HPMS memo,[72] concerning the definition of 'primarily health related' with respect to supplemental benefits. Under a longstanding interpretation of the MA statute and regulations, CMS defines a mandatory or optional supplemental health care benefit as an item or service (1) not covered by original Medicare, (2) that is primarily health related, and (3) for which the plan must incur a non-zero direct

[71]https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
[72]https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011202/HPMS%20Memo%20Primarily%20Health%20Related%204-27-18.pdf

medical cost. Only an item or service that meets all three conditions could be proposed and covered as a supplemental benefit in a plan's PBP. We proposed to codify this policy at § 422.100(c)(2)(ii) by setting forth these criteria as requirements that supplemental benefits must meet.

The current regulation text at § 422.100(c)(2) focuses on distinguishing between mandatory supplemental benefits and optional supplemental benefits. We proposed to re-designate the substance of that current regulation text as new paragraphs (c)(2)(i)(A) and (B). We proposed to codify our longstanding definition of supplemental benefits as three requirements that must be met by a supplemental benefit at paragraph (c)(2)(ii). In paragraph (c)(2)(ii)(A), we proposed to codify that a supplemental benefit must be primarily health related, using a standard discussed in more detail in this section of this final rule and with specific text to address SSBCI. In paragraph (c)(2)(ii)(B), we proposed to codify that a MA organization must incur a non-zero direct medical cost in furnishing or covering the supplemental benefit to verify that the benefit is medically related, with specific text to address special supplemental benefits for the chronically ill (SSBCI), discussed in more detail in section II.A of the proposed rule and section II.A of the final rule titled "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," which appeared in the Federal Register on June 2, 2020 ("June 2020 Final Rule") (85 FR 33796, 33800 through 33805). Finally, in paragraph (c)(2)(ii)(C), we proposed to codify the requirement that the supplemental benefit is not covered by Medicare. The portion of a benefit where coverage is more generous or greater coverage of a Medicare Part A or Part B benefit – such as coverage of more inpatient days or coverage with lower cost sharing compared to Medicare – is a supplemental benefit. However, an MA plan may not cover a Part D drug or reduce Part D cost sharing as an MA supplemental benefit. Under § 422.500, an MA plan that covers any Part D benefit must comply with the Part D regulations in part 423 and, therefore, must be a Part D sponsor of a Part D plan. In addition, § 422.266(b)(1) provides that

an MA plan may use its rebates to buy down a Part D premium, including the premium for supplemental drug coverage described at § 423.104(f)(1)(ii).

1. Primarily Health Related

We explained in the proposed rule that, as discussed in the 2019 Call Letter and an April 2018 HPMS memo, CMS currently interprets "primarily health related" as meaning that the item or service is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. We are clarifying in this final rule that the current interpretation is that in order for a service or item to be "primarily health related", it must *diagnose, prevent, or treat an illness or injury*, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization; these key words ("diagnose, prevent, or treat an illness or injury") were inadvertently left out of the proposed rule. Using this interpretation, CMS has provided MA plans with flexibility in designing and offering supplemental benefits that may enhance beneficiaries' quality of life and improve health outcomes. We proposed to codify that supplemental benefits must be primarily health related, with this definition, at § 422.100(c)(2)(ii)(A).

Examples of supplemental benefits include: dental, vision, adult day health services, home-based palliative care, in-home support services, support for caregivers of enrollees, stand-alone memory fitness, expanded home and bathroom safety devices and modifications, wearable items such as compression garments and fitness trackers, over-the-counter items, and expanded transportation for medical purposes. A supplemental benefit is **not** primarily health related under this definition if it is an item or service that is solely, or primarily used for cosmetic, comfort, general use, or social determinant purposes. Also, to be primarily health related, the benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a care plan, if not directly provided by one. Enrollees are not

currently required to get physician orders for supplemental benefits (for example, OTC items), and requiring it now would impose new restrictions on MA plans and potentially cause large administrative burden and interruptions in care. Therefore, our proposal included continued use of the "recommended" standard as part of interpreting and applying this component of the definition of supplemental benefit. We note that supplemental benefits must also be medically appropriate to be primarily health related; if a service or item is not medically appropriate, it is not primarily health related. This is consistent as well with our longstanding guidance in Chapter 4, section 30.2, of the Medicare Managed Care Manual that supplemental benefits must be medically necessary. We will continue our current interpretations and guidance in codifying existing policy on this issue.

We noted in the proposed rule that the BBA of 2018 amended section 1852(a)(3) of the Act to permit MA plans to offer additional supplemental benefits that are not primarily health related for chronically ill enrollees, beginning January 1, 2020. In section II.A of the proposed rule, we proposed a regulation, to be codified at § 422.102(f), to set standards for special supplemental benefits for chronically ill enrollees (SSBCI); we finalized that regulation largely as proposed in the June 2020 Final Rule. We explained that the expansion of supplemental benefits for chronically ill enrollees would not affect our proposed definition of "primarily health related" and how it applied to traditional supplemental benefits under our proposal at § 422.100(c)(2)(ii), but we proposed to exclude SSBCI from compliance with the requirement that supplemental benefits be primarily health related at § 422.100(c)(2)(ii)(A). We also explained that the standard that supplemental benefits be primarily health related was a higher standard than the requirement that have reasonable expectation of improving overall health.

2. Uniformity Requirements

We also proposed to codify an existing policy regarding the requirement that benefits covered by an MA plan be uniform for all enrollees in the plan. There are several MA regulations that address uniformity, including the definition of MA plan at § 422.2, the

requirement at § 422.100(d), and the bidding and premium requirements at §§ 422.254(b) and 422.262(c). As explained in the final rule, published in April 2018, titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, ("April 2018 final rule") (83 FR 16440, 16480-85), CMS has determined that providing access to supplemental benefits that are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA program. We solicited comments on this reinterpretation and finalized it in that prior rulemaking. In response to those comments and based on our further consideration of this issue, we provided guidance to MA organizations in both the April 2018 final rule and a subsequent HPMS memo[73] released April 27, 2018. We proposed to codify this reinterpretation specifically in regulation text at § 422.100(d)(2).

The regulations on MA uniform benefits implement both section 1852(d) of the Act, which requires that benefits under the MA plan are available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In 2018, in issuing a final rule and guidance for contract year 2019, we determined that these statutory provisions and the regulation at § 422.100(d) meant that we had the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, *all* enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same. We explained this in the proposed rule and that our interpretation means that there must be some nexus between the health status or disease state and the specific benefit package

[73]https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011207/HPMS%20Memo%20Uniformity%20Requirements%204-27-18.pdf

designed for enrollees meeting that health status or disease state. We proposed to redesignate paragraph (d)(2) as (d)(2)(i) and add new paragraph (d)(2)(ii) to specifically state that MA organizations may reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same and that there is some nexus between the health status or disease state and the tailored benefits. We explained in the proposed rule that we review MA benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations; this review applies various standards in addition to the uniformity requirements.

We thank commenters for helping inform CMS' policy on supplement benefit requirements. We received approximately 27 comments on this proposal; we summarize them and our responses follow:

Comment: Many commenters supported this proposal.

Response: We thank commenters for their feedback.

Comment: A few commenters requested CMS provide greater detail on allowable supplemental benefits and confirm examples. Additionally, commenters requested that CMS update the Medicare Managed Care Manual to include these new policies.

Response: We believe that our discussion in the proposed rule explaining the proposal we are finalizing provides sufficient guidance for MA organizations on this topic in this context. The proposal was to codify existing guidance. In addition to the CY2019 Call Letter (specifically about the expanded definition of "primarily health related") and the April 2018 HPMS memo on the Reinterpretation of "Primarily Health Related" for Supplemental Benefits, Chapter 4 of the Medicare Managed Care Manual provides extensive guidance about basic benefits and supplemental benefits offered by MA plans. Specifically, section 30 of Chapter 4 discusses a number of examples. Additionally, CMS will consider additional subregulatory

guidance, including manual updates, as necessary in implementing and administering the legal standards for MA benefits.

Comment: Some commenters stated concern that recent changes to the Medicare Communications and Marketing Guidelines (MCMG) could also increase confusion about supplemental benefits among enrollees.

Response: As stated in the April 2018 HPMS memo on primarily health related supplemental benefits, MA plans are responsible for clearly identifying what will and will not be covered in the plan's Evidence of Coverage (EOC). Any limitations on coverage should be clearly noted in the EOC. Organizations are encouraged to provide explanations to establish how a supplemental benefit, particularly a new or novel benefit, is primarily health related or how coverage of an item or service will be limited to when it is primarily health related. Activities and materials that mention benefits are considered marketing (as defined under §§ 422.2260 and 423.2260) and are subject to the requirements at §§ 422.2263 and 423.2263 (General marketing requirements). Please refer to section V.E. of this final rule, where we address proposals to codify our current policies for marketing and communications by MA and Part D plans. We believe that our requirements for how MA plans market their benefits and how the scope and rules for coverage must be disclosed annually to enrollees ensure that confusion is minimized for enrollees. As we monitor the MA program and complaints (submitted to 1-800-Medicare and otherwise), we will consider if additional guidance or rulemaking is necessary to address unforeseen confusion among beneficiaries.

Comment: Some commenters expressed concern that original Medicare beneficiaries do not have access to supplemental benefits. One commenter stated that MA plan premiums for supplemental benefits may pose a barrier to the receipt of supplemental benefits. One commenter suggested CMS introduce models that allow original Medicare beneficiaries access to supplemental benefits.

Response: Comments regarding Original Medicare beneficiaries' access to MA plans supplemental benefits are out of scope for this regulation. As to the comment about MA premiums, sections 1853 and 1854 of the Act address how MA plan premiums are defined and charged. Further, section 1852 of the Act explicitly authorizes MA organizations to offer supplemental benefits to their enrollees and section 1854 of the Act addresses how MA plans that bid below the payment benchmark for their service area may use a portion of the amount by which the benchmark exceeds the bid to pay the premiums for supplemental benefits. Information about premiums and supplemental benefits is available during the annual coordinated election period for beneficiaries to use in making enrollment decisions.

Comment: A commenter suggested CMS allow MA plans the ability to offer supplemental benefits at a county level within a multi-county service area plan.

Response: Plans segments are county-level portions of a plan's overall service area. As discussed in the April 2018 Final Rule (83 FR 16486), §422.262(c)(2) permits MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment so long as the supplemental benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. MA plan segments currently may be composed of one or more counties within the service area.

Comment: A few commenters expressed concern that supplemental benefits are not visible in the MPF.

Response: We will take this recommendation under consideration as we continue to refine the MPF tool.

Comment: A commenter expressed concern about the lack of community-based providers available to provide supplemental benefits.

Response: CMS is prohibited from requiring MA plans to contract with specific providers under section 1854(a)(6)(B)(iii) of the Act and § 422.256(a)(2)(i), but so long as they comply with the standards established for provider contracting in part 422, subpart E, MA organizations

may contract with community-based providers. Further, § 422.112(b)(3) provides for coordinated care MA plans to include community-based services in their plans for coordination and continuity of care for enrollees. In addition, § 422.112(b)(3) specifically states that MA coordinated care plans are required to "coordinate MA benefits with community and social services generally available in the area served by the MA plan." MA plans may contract with community-based organizations to provide supplemental benefits that are compliant with the statutory and regulatory requirements. For example, an MA plan could elect to offer a meals or food/produce supplemental benefit (so long as the benefit is primarily health related and the plan incurs a non-zero direct medical cost consistent with § 422.100(c)(2)) and pay a community-based organization for furnishing the covered benefit. We understand that in some areas there may be a limited number of community-based providers and hope that the increased supplemental benefit flexibilities discussed in this rule encourage increased opportunities for community provider participation.

Comment: A commenter requested CMS provide additional guidance on how plans can make sure that supplemental benefits meet the "primarily health related" requirement.

Response: We suggest plans review the April 27, 2018 memo titled "Reinterpretation of "Primarily Health Related" for Supplemental Benefits". In addition, Chapter 4 of the Medicare Managed Care Manual contains guidance on permissible supplemental benefits, which gives MA organizations and the public an understanding of which benefits we have previously determined to meet this standard. The standard we are finalizing at § 422.100(c)(2)(ii)(A) provides that to be primarily health related, a benefit must – as a primary matter - diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/ psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization. A supplemental health benefit proposed by an MA organization must be reasonably and rationally encompassed by this standard and may not have a primary purpose that is outside of this standard. The primary purpose of an item or service is determined by national

typical usages of most people using the item or service and by community patterns of care. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee's healthcare needs and be medically appropriate for the enrollee. While we do not require that the physician or health care professional prescribe or order an item or service for it to be considered primarily health care, we believe that recommendation by a licensed provider as part of a care plan is an important sign that an item or service meets this standard. We cannot provide an exhaustive list of items and services that potentially are primarily health related. We consider this sufficient general guidance for plans to make sure that supplemental benefits meet the "primarily health related" requirement.

Comment: In light of COVID-19, one commenter suggested CMS provide additional flexibility to provide supplemental benefits for high-risk populations that must remain in their homes. This commenter suggested CMS allow plans to provide home delivered meals, grocery, produce, and non-medical transportation for this population.

Response: We are not finalizing a change to the proposed standards for defining supplemental benefits to specifically address the COVID-19 public health emergency. Earlier in 2020, CMS issued guidance[74] to MA plans, in response to the unique circumstances resulting from the outbreak of COVID-19. CMS exercised its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements that was adopted in a 2008 final rule (73 FR 43628); CMS allowed MA plans to implement additional or expanded benefits that address medical needs and access to healthcare raised by the COVID-19 outbreak, such as covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID-19 public health emergency. For CY2021, CMS issued additional guidance on December 28, 2020 titled "Contract Year 2021 Coronavirus Disease 2019 (COVID-19) Permissive Actions FAQ" stating

[74] https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf

that we will continue this use of enforcement discretion in connection with the prohibition on mid-year benefit enhancements.

Comment: A commenter requested that CMS provide additional clarity around what is intended by CMS's statement in the preamble and referenced guidance that a primarily health related benefit should be recommended by a licensed medical professional as part of a care plan and to clarify what is acceptable when the supplemental benefit is not directly provided by a licensed medical professional and the enrollee does not receive case management services and an individual care plan.

Response: A medical professional does not have to be the individual or entity furnishing the supplemental item or service. We recognize that there are scenarios in which a medical professional would not be furnishing a service (for example, meals). However, the item or service must still meet the regulatory criteria for a supplemental benefit at § 422.100(c)(2)(ii)(A) being finalized here, that is to be primarily health related, a benefit must benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health. Recommendation by a medical professional, even if not part of a formal care management or care coordination plan, is an important indicator that a particular item or service is being furnished for primarily health-related purposes but is not necessarily the only indication. The primary purpose of an item or service is determined by national typical usages of most people using the item or service and by community patterns of care and/or by established research or medical compendia and journals about such item or service. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee's healthcare needs and must be medically appropriate for the enrollee. We expect MA plans to have procedures and processes in place to ensure a reasonable determination is made that the covered benefit is medically appropriate for the enrollee in the event that it is not practical for a medical professional to make a specific recommendation or evaluation.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, substantively as proposed but with clarifications, the proposed amendments to § 422.100(c) to restructure the regulation text and add the three requirements for an item or benefit to be a supplemental benefit and to§ 422.100(d)(2) to restructure the regulation text and add a provision explicitly addressing how supplemental benefits that are tied to disease state or health status may meet the uniformity requirement and be offered as supplemental benefits. Although we are finalizing this provision as applicable beginning January 1, 2022 (2022 calendar/contract year), it effectively applies to 2022 bids and all plan materials and activities affecting or in furtherance of facilitating enrollment for the 2022 contract year. Therefore, the final rule will govern most plan communication and marketing activities and materials during the second half of 2021. Furthermore, it codifies current policies so we encourage MA organizations to take this final rule into account immediately.

In addition, we are finalizing § 422.100(c)(2)(ii)(A) with clarifying changes. First, we are adding the phrase "prevent, or treat an illness or injury," which was mistakenly left out of the proposed rule but is part of the current policy we are codifying. Second, we are finalizing the regulation text in this paragraph with semi-colons between each phrase to make it clear that fulfilling one of the listed functions as the primary function is sufficient for an item or service to be considered primarily health related under this final rule. Third, we are adding text to clarity that supplemental benefits must not be items and services covered by Parts A, B or D; to further clarify this point, we added the words "Parts A, B, and D" in parenthesis next to the word Medicare in paragraph (c)(2)(ii)(C). The proposal was to codify already existing guidance and

practices and we stated that it is not expected to have additional impact above current operating expenses; this final rule is the same on this point.

D. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

As noted in the February 2020 proposed rule, based on CMS' authority under sections 1856(b)(1) and 1857(e)(1) of the Act, CMS, in 2014, authorized MA organizations, including those offering a Medicare Medical Savings Account (MSA) plan option, to offer rewards and incentives (R&I) programs (79 FR 29956, May 23, 2014). We adopted this regulation that authorized Part C R&I programs for a number of reasons. In some cases, MA organizations wished to extend rewards and incentives already offered to their commercial members to their Medicare enrollees. Many MA organizations wished to sustain their current R&I programs as well as stay competitive with other MA organizations with comparable offerings. Additionally, there is evidence suggesting that health-driven reward and incentive programs may lead to meaningful and sustained improvement in enrollee health behaviors and outcomes.

Our experience has shown that most R&I programs offered by MA plans fall into the following four areas:

(i) Specified use of plan benefits such as rewards provided for obtaining preventive benefits at specified intervals;

(ii) Following a specified program that promotes exercise and/or good nutrition;

(iii) Participating in specified programs that educate on health matters and/or self-management of nutrition and exercise;

(iv) Specified utilization of plan resources such as hotlines, patient portals, and similar items that facilitate promotion of health.

In the February 2020 proposed rule, CMS proposed to amend § 422.134 to codify the guidance we have given since adopting the regulation in 2014, unify principles governing MA rewards and incentive programs, clarify the requirements of the regulation, and clarify flexibilities available to MA organizations under the regulation. Readers are directed to the proposed rule for a

detailed discussion of the proposal (85 FR 9204 through 9108) as we are not fully repeating our proposal here.

In this final rule, CMS is re-organizing the regulation at 42 CFR 422.134 to clarify and codify existing guidance that reflects how we have addressed inquiries about the R&I program over the past 5 years. The reorganization of 42 CFR 422.134 is outlined as follows: a) definitions, b) the option for an MA plan to offer an R&I program subject to the requirements of this section, c) the requirements and prohibitions for target activities, d) requirements and prohibitions on the offering of reward items, e) marketing requirements, f) disclosure requirements, and g) miscellaneous requirements, for example, bids, sanctions, and grievances. As finalized, § 422.134 is substantially reorganized compared to the current regulation. The finalized policy presented here differs from the NPRM in the following areas: We have:

i) Further clarified the definition of qualifying individual at paragraph (a),

ii) Moved the requirements of uniformity of the target activity and provision of accommodations from paragraphs (c)(2)(iii)(A) and (B) to paragraphs (c)(1)(iv) and (v),

iii) Modified the requirement of providing accommodations (moved from paragraph (c)(2)(iii)(B) to paragraph (c)(1)((v)) to respond to commenter concerns,

iv) Reworded the requirement of uniformity in the reward item at paragraph (d)(1)(i),

v) Removed the prohibition of midyear changes at paragraph (g)(iv) and,

vi) Although not changing the regulatory text, clarified in the preamble the requirements at paragraph (d)(1)(iii).

The details of these changes including comments and responses and the rationale for the changes are provided in their respective discussions below.

We are not specifically addressing here those aspects of our proposal that were merely moving a provision currently in § 422.134 to a different paragraph and on which we did not

receive substantive comments. See Table E6 for a comparison of the current regulation text with the regulation text we are finalizing in this rule.

We now discuss the new requirements proposed in the February 2020 proposed rule, the comments received, and our decision about finalization.

Definitions. We proposed to codify various definitions at § 422.134(a), including "target activity," "reward item," "incentive item," and "reward and incentive program." Along with a proposed definition, we also introduced the term "qualifying individual" as a way to refer to the individual who could be eligible for or earn a reward; we proposed that a qualifying individual, in the context of a plan-covered health benefit, means any plan enrollee who would qualify for coverage of the benefit and satisfies the plan criteria to participate in the target activity; in the context of a non-plan-covered health benefit, a qualifying individual means any plan enrollee who satisfies the plan criteria to participate in the target activity.

As we considered the proposed rule, we believe that the definition of "qualifying individual" can and should be refined even though no commenter specifically raised the issue. To avoid any confusion about the limitations plans may set regarding who may participate in target activities, we are finalizing the definition with modifications from the proposal. In the context of a plan-covered health benefit (whether an Original Medicare benefit, an SSBCI, or other supplemental benefit), qualifying individual refers to any individual meeting coverage criteria. We introduced this definition to communicate how MA plans should offer reward uniformly and without discrimination to all enrollees and to avoid problems with uniformity discussed in detail below. For example, it is not a violation of uniformity if a plan offers rewards and incentives for any qualifying individual who gets a mammogram. While it is true that many men and some women do not qualify for mammograms, the plan is not violating uniformity in this example since we now define uniformity as requiring plans offer R&I to "all qualifying individuals" which in the case of plan-covered benefits is different than "all enrollees." CMS' intention in the proposed rule was to codify current CMS reward and incentive policy, not to add

new criteria for program participants to qualify for participation in an R&I program or to earn a reward. The proposed definition, by including references to satisfying the MA plan's criteria for participating in the activity, suggested that MA plans could limit participation in R&I programs in a broader manner than we intended.

We received no comments on the proposed definitions in paragraph (a) itself and are finalizing paragraph (a) substantially as proposed for the reasons provided in the proposed rule. We also are finalizing edits in the definition of qualifying individual so that it is clearer in setting forth how enrollees are to be offered access to reward programs: *Qualifying individual* in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Direct involvement of enrollee. At § 422.134(c)(1)(i), we proposed to codify our existing guidance requiring that target activities must directly involve the qualifying individual and performance by the qualifying individual. Under our proposal, the completion of activities by caregivers would not qualify for a reward item.

We received no comments on this provision and are finalizing it as proposed for the reasons provided in the proposed rule

Level of completion requirements. At § 422.134(c)(1)(ii), we proposed to clarify that target activities must be specified (by the MA organization) in detail as to the level of completion needed in order to qualify for a reward item. We explained in the proposed rule how this was based on current § 422.134(c)(1)(i), which requires a reward to be offered in connection with an entire service or activity, and our current guidance, which provided flexibility for MA organizations to identify "an entire service or activity." Our proposal was essentially to codify our current guidance, which permitted MA organizations to offer and furnish rewards for completion of components of a multi-part activity so long as the MA organization reasonably defined the scope of the entire activity. For example, an MA organization may offer an eight-

session weight management class; under this example, the MA organization may offer and provide a reward for either completion of all eight sessions of this eight-session weight management class or for attendance at each individual session of the weight loss class that the enrollee attends. Both of these scenarios are permissible as long as the plan (or R&I program) defines the target activity that will be rewarded.

Comment: A few commenters requested that CMS allow provision of the entire incentive upfront, rather than after the incentivized benefit has been utilized, to capitalize on humans' innate tendency toward loss aversion.

Response: We thank the commenters for their interest in incentivizing enrollees. We however are not adopting the recommended change. The R&I program, although not a benefit, is an expense to the Medicare Advantage program. Certain safeguards, such as a requirement of actual completion of activities to receive the reward, therefore, are necessary to avoid inappropriate use of Medicare dollars. In addition, we are mindful of how section 1851(h)(4) of the Act requires the adoption of standards that prohibit MA organizations from providing for cash, gifts, prizes, or other monetary rebates as an inducement for enrollment *or otherwise*; providing the reward in advance of the performance of the health related activity could create the appearance that MA plans are providing items of value as a prohibited inducement.

We are finalizing this provision as proposed for the reasons provided in the proposed rule and indicated in the response to comments.

Health related activity requirements. At § 422.134(c)(1)(iii), we proposed to move the standard stated in the current regulations that R&I programs reward enrollees "in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources." We proposed to move this requirement to § 422.134(c)(1)(iii) to more clearly outline that target activities must be health-related by doing at least one of the following: promoting improved health, preventing injuries and illness, or promoting the efficient use of health care resources.

Comment: Some commenters praised the clarity in the enumeration at § 422.134(c)(1)(iii).

Response: We thank the commenters for their support. We take this opportunity to clarify that we interpret the reference to the efficient use of health care resources in the final regulatory text as capable of being determined from either the perspective of the plan or the beneficiary. We are finalizing this provision as proposed.

Uniformity: To achieve greater clarity and to address issues raised by commenters, we are finalizing § 422.134(c) with several changes from the NPRM in connection with uniformity and non-discrimination requirements.

The requirements of uniformity and provision of accommodations (that is, that rewards must be offered uniformly to all qualifying individuals and that accommodations must be provided to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity. for target activities) were proposed to be codified at § 422.134(c)(2)(ii) as standards to ensure that anti-discrimination requirements were met. We are finalizing these concepts as part of the standards for target activities, at § 422.134(c)(1)(iv) and (v). Upon reflection and based on the comments requesting clarification related to these concepts, we believe that uniformity and provision of accommodations are positive statements and best classified as requirements for target activities at § 422.134(c)(1) rather than as part of demonstrating compliance with a prohibition against discrimination. We believe these standards serve purposes in addition to anti-discrimination, such as encouraging participation in health related activities in the broadest way possible even if limiting access to a reward would not necessarily be based on a prohibited basis like health status, race or sex. This reorganization of how these standards apply provides greater clarity and transparency for the application of § 422.134.

We now discuss each of these requirements separately by presenting the comments we received on them.

Uniformity: We are finalizing the requirement that a target activity must uniformly offer any qualifying individual the opportunity to participate in the target activity at § 422.134(c)(1)(iv). This means that target activities must be designed so that they are uniformly offered to all qualifying individuals, as that term is defined in paragraph (a). For example, regarding an R&I program that provides a reward for obtaining a mammogram, providing rewards only to those enrollees who have never before obtained a mammogram would violate the uniformity requirement as it would leave out members who have previously obtained a mammogram but are otherwise qualifying individuals. We believe that this uniformity requirement is key to preventing discrimination against different groups of enrollees and consistent with our current guidance in section 100 of Chapter 4 of the Medicare Managed Care Manual. This requirement ensures that reward programs encourage all enrollees to be actively engaged in their health care and activities that ultimately improve and sustain their overall health and well-being.

The purpose of CMS implementing the R&I program requirements this way is to incentivize all individuals to engage in target activities that will meet one of three health-related goals. Enrollees who have previously taken steps to care for their health should be incentivized to continue to do so as much as individuals who are taking such steps for the first time.

Comment: Some commenters suggested we allow R&I programs to target a beneficiary's clinical status, for example, those who would most benefit from the incentivized intervention or those who are not using a benefit. Another commenter wanted to reward women who had not had mammograms in three years with a higher reward to encourage them to get mammograms more regularly by providing a higher reward. These commenters noted that recent legislative and regulatory activities have permitted Medicare Advantage plans to tailor health benefits to targeted populations, ensuring they meet the unique needs of specified groups of beneficiaries based on diagnosed conditions or diseases. The commenters indicated that, in the same way, CMS should explore permitting Medicare Advantage plans to tailor R&I programs for

beneficiaries to meet the needs of clearly defined groups of beneficiaries. The commenters believed this could improve participation in care and improve outcomes by incentivizing compliance in clinical recommendations such as attending office visits or participating in wellness programs tailored to their needs.

Response: We thank the commenters for raising these issues. In response to the suggestion that we allow R&I programs to target those who are not using a benefit, we note that this would not be allowed because it would not be offered uniformly to all qualifying individuals and, as explained above, goes against the goal of R&I programs. In response to the suggestion that CMS allow an R&I program to reward women who had not had mammograms in three years with a higher reward, we note that, as worded by the commenter, this violates the general non-discrimination provision at 42 CFR 422.134(g)(1) because the reward would only go to women. If the target activity had instead been formulated by the commenter as targeting any qualifying individual who has not had a mammogram in three years, this would still not be allowed since it does not offer the target activity uniformly to all qualifying individuals but only to those individuals who have not had a mammogram in three years. Providing different rewards to those completing a mammogram based on their past history of mammogram services would violate the uniformity of reward requirement at 42 CFR 422.134(d)(1)(i), which is discussed further below.

We believe the reference to recent legislative and regulatory activity refers to Special Supplemental Benefits for the Chronically Ill (SSBCI) recently codified in CMS-4190-F1. We are not persuaded that the same approach is necessary for R&I programs because SSBCI is a benefit but rewards and incentives are not benefits. In the case of SSBCI, these special types of benefits are allowed to be targeted to enrollees who specifically need them while enrollees who do not need SSBCI are not allowed these items; contrastively, R&I is beneficial for all enrollees irrespective of their past since both those who are currently using benefits as well as those who are not currently using benefits can be incentivized to either start using the benefit or continue using the benefit. CMS believes the intent of R&I programs to incentivize all enrollees to

engage in healthy behaviors to improve health outcomes applies universally. Maximizing access to R&I programs by enrollees will result in broader benefits and broader engagement in health related activities. Further, ensuring broad access by any qualifying enrollee to the target activity (and therefore access to earning the reward) ensures that a beneficiary will not be persuaded to enroll in a particular plan based on the reward program and subsequently learn that he or she is not able to participate in the reward program because the target activity is limited to enrollees who have never engaged in it.

However, an MA plan may design an R&I program that could effectively target enrollees with a specific condition or disease state and for those who would benefit most from the incentivized interventions (as suggested by commenters) without violating the non-discrimination or uniformity requirements being finalized in § 422.134. Plans may do this by rewarding qualifying individuals for participating in target activities that are covered benefit items and services as these benefits must be medically necessary, or for SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee, for an individual to obtain. As finalized, § 422.134 does not require a plan to cover an item or service when it is not medically necessary, even if getting that particular covered benefit is the target activity for an R&I program. Therefore, these types of target activities are already tailored to the qualifying individual's needs based on a specific condition or disease state and would be available to those who would benefit most from the incentivized intervention. For example, an R&I program designed to offer rewards to any qualifying individual for using glucose test strips would likely help an MA plan reach their diabetic enrollee population, as glucose test strips are generally only considered medically necessary if an enrollee is diabetic, while also allowing other members, in rare instances, who may need glucose test strips an opportunity to be rewarded for engaging in the healthy behavior as well.

We are finalizing the uniformity requirement for target activities at paragraph (c)(1)(iv) as proposed (with the move from paragraph (c)(2)(iii)(A) to paragraph (c)(1)(iv) discussed above) for the reasons provided in the proposed rule and our discussion in this final rule.

Accommodations: We next discuss the requirement of providing accommodations at § 422.134(c)(1)(v) (moved from § 422.134(c)(2)(iii)(B)) and comments received on this requirement. Proposed paragraph (c)(1)((v) stated a requirement for an MA organization to provide accommodations to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

Comment: Comments on our proposal that MA organizations provide accommodations to qualifying individuals were generally supportive. The commenters generally stated that providing accommodations to those who wish to participate, but are without the means to do so, will allow the benefits of these R&I programs to positively impact the health of a broader population of members. However, a commenter pointed out that an accommodation should not be permitted if such an accommodation would contradict the purpose of the target activity. This commenter agreed that as a general matter plans should accommodate members without internet access wherever possible to offer an alternative offline activity consistent with the purpose of the target activity. For example, a plan that rewards members who report their exercise online can accommodate a member without internet access by allowing that member to verbally report their exercise to a call center. In this example, rewarding the alternative activity serves the purpose of the original target health activity. However, where the target activity is intended to promote the efficient use of resources, such as agreeing to electronic delivery of documents, the commenter statutes that it would not reasonable to require plans to offer an offline alternative, as an offline activity would not promote the efficient use of resources and would be directly contrary to the reward's purpose.

Response: We appreciate the support for the requirement that MA organizations provide accommodations. As stated previously, we believe that this requirement will ensure that R&I

programs are broadly based and encourage enrollees to be actively engaged in their health care and, ultimately, improve and sustain their overall health and well-being. We agree with the commenter's concern and are therefore finalizing the requirement for accommodations with additional text to provide that the required accommodation be consistent with the goal of the target activity. We encourage MA organizations to take into account the resources, abilities, and characteristics of its enrolled population in devising R&I programs and in identifying target activities. As noted above, we believe moving the accommodation requirements from paragraph (c)(2)(iii)(B) to paragraph (c)(1)(v) provides greater clarity and transparency in imposing this as an affirmative standard for all target activities. It also removes any implied limitation that accommodations are only necessary to ensure that a prohibited basis for discrimination (such as race, ethnicity, sex or health status) is not being used. As illustrated in our example in the proposed rule and our current guidance in section 100.2 of Chapter 4 of the Medicare Managed Care Manual, the requirement for accommodations is broadly interpreted in order to ensure access for all qualifying individuals.

Part D target activities. We proposed, at § 422.134(c)(2)(i), to prohibit target activities that are related to Part D benefits because the provisions in Part 422 pertain to Medicare Advantage Part C and not to Part D. This is consistent with our subregulatory guidance in Chapter 4 of the Managed Care Manual as well as with responses to comments in the 2014 rule which initially authorized MA plans to use R&I programs (79 FR 29917). Should a Part D R&I program be developed, it will be a separate provision from this one, with regulatory language added to Part 423. We note that in section IV.F of this final rule, we are finalizing a narrow reward program provision for Part D plans.

Comment: We received several comments from stakeholders urging CMS to allow Part D sponsors to offer rewards for target activities related to Part D benefits, such as beneficiary adherence to a medication regimen(s). Commenters generally believed that such an allowance could benefit enrollees by improving compliance. One commenter noted that the specific

application of R&I for healthy prescription drug behaviors of enrollees of MA-PD plans is being tested by CMMI in the MA VBID model. An initial evaluation based on the first year of experience found that plans were able to drive more appropriate use of medical services by providing rewards and incentives. Beginning in plan year 2019, plan sponsors were able to include R&I for prescription drugs as well; however, these programs have not yet been evaluated. Commenters recommended allowing Part D R&I programs for both MA-PD plans as well as stand-alone prescription drug plans.

Response: We thank the commenters for their recommendations and the citations of similar programs offered elsewhere. CMS regularly reviews the various models being tested by the Center for Medicare and Medicaid Services Innovation Center to ascertain what works and what can be incorporated into our general programs. An example of CMS's commitment to new ideas may be found in Section IV.F of this final rule which creates a limited R&I program for the real time benefit tool. We note that Section IIIC of this final rule presents a comment similar to the comment just cited, requesting that R&I be used to incentivize return of unused opioids. However, as noted in Section IIIC and as noted above, it is out of scope of § 422.134 to allow a Part D R&I program. CMS did not propose a regulation to authorize general Part D reward and incentive programs and therefore is not finalizing such a new regulation.

We are therefore finalizing § 422.134(c)(2)(i) as proposed and reiterate that it does not authorize rewards or incentives tied to Part D benefits, either by MA organizations that offer MA-PD plans or by other Part D sponsors that offer stand-alone Part D plans.

Non-Discrimination and Health Status. R&I programs must not be discriminatory; there is a general prohibition about that proposed and finalized at § 422.134(g)(1). At § 422.134(c)(2)(ii), we proposed to revise and clarify the non-discrimination requirements in the current regulation and codify our current guidance on those requirements. Proposed at paragraph § 422.134(c)(2)(ii)(C) and finalized at § 422.134(c)(2)(ii), this regulation generally prohibits target activities from discriminating against enrollees and requires specifically that MA

organizations comply with § 422.134(g)(1) and not design a reward program that is based on the achievement of a health status measurement. Current sub-regulatory guidance provides that non-discrimination, which is part of the current regulation at § 422.134(c)(1)(ii), requires in part that a target activity not consist of the achievement of a specific health status or measurement or outcome as this would be discrimination based on health status. For example, an MA organization would be prohibited from creating a target activity that stipulates achieving a certain weight, or achieving a certain Body Mass Index (BMI) score. However, a target activity could consist of some combination or all of the following: maintaining an exercise program, eating nutritious meals (with "nutritious" being further defined by the plan), and taking weight measurements at periodic intervals. Similarly, an MA organization would be prohibited from creating a target activity that stipulates achieving a blood pressure reading in a certain range but a permissible target activity could consist of taking blood pressure measurements at periodic intervals.

We did not receive any comments that specifically discussed this part of the proposed rule. We are finalizing the provisions at § 422.134(c)(2)(ii) as proposed for the reasons provided in the proposed rule.

Offered Uniformly. We proposed at new paragraph (d)(1)(i) to require reward items to be offered uniformly to any qualifying individual who performs the target activity. In the proposed rule, we explained that this would codify our current subregulatory guidance, which ties the standard to the non-discrimination requirement in the current version of § 422.134(b)(2) that reward programs must be designed so that all enrollees are able to earn rewards.

We did not receive any comments specific to the proposed requirement proposed in paragraph (d)(1)(i) that reward items be offered uniformly to qualifying individuals. However, in order to avoid conflating this requirement with the uniformity requirement we are finalizing at paragraph (c)(1)(iv) regarding target activities, we are finalizing paragraph (d)(1)(i) as a requirement that reward items must be offered identically to any qualifying individual who

performs the target activity. This requirement is to ensure that each enrollee has access to the same reward items (or same choice among reward items if applicable). While related to the uniformity requirement for target activities, it is designed to address the potential that some enrollees would receive different, potentially more valuable, reward items compared to other enrollees. This requirement is a reflection of the non-discrimination principles underlying several other requirements being finalized in § 422.134. We believe that this additional standard is necessary to ensure that R&I programs are operated in an equitable way and that the use of different reward items does not result in more incentive being offered by the MA plan to certain enrollees. As discussed previously, R&I programs should be broadly based and operated for the benefit of all enrollees or as many enrollees as possible; using identical rewards for each qualifying individual who performs the same target activity contributes to that goal.

Note that throughout § 422.134 we use the term "perform" or "performance." However at paragraph (c)(1)(ii) we refer to the "level of completion needed in order to qualify for the reward." We therefore clarify that our use of "perform" refers to the performance of the entire health related activity. At paragraph (c)(1)(ii) we refer to the "level of completion needed" because rewards must be earned by completing an entire service or activity (or combination of services/activities), as established by the MA plan, and may not be offered for completion of less than any/all required component(s) of the eligible service or activity. This requirement allows CMS and MA plans to interpret the value of a reward or incentive in relation to the service or activity for which it is being offered. Plans are expected to reasonably define the scope of a health related service or activity within their RI Program design and assign a value of the reward accordingly. For example, a plan may decide to offer rewards and/or incentives for participation in a smoking cessation program. The plan may decide to give smaller rewards for each class or counseling session attended or may offer a single, larger reward for completing a pre-determined number of classes or counseling sessions.

We did not receive any comments that specifically discussed this part of the proposed rule. We are finalizing the provisions at § 422.134(d)(2) as proposed for the reasons provided in the proposed rule and.

Direct and Tangible. At § 422.134(d)(1)(ii), we proposed, consistent with current guidance, to require that reward items be direct and tangible. For example, a reward item cannot consist of a charitable donation.

We received no comments on this provision and are finalizing it as proposed for the reasons provided in the proposed rule.

Transfer of ownership. At § 422.134(d)(1)(iii), we proposed to require that the reward item must be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless if the enrollee is likely to use the reward item after the contract year.

Comment: Several commenters pointed out that this provision may pose operational concerns. For example, in late December an enrollee may complete a target activity that the plan finds out about at the beginning of the next plan year, which is outside of the time the enrollee could claim the reward as the guidance currently states.

Response: We agree with the commenters' concerns. We believe the language in the NPRM did not adequately communicate our intent that the R&I program be based on activities completed during the contract year. As stated in the NPRM, we believe that MA plans should not be able erase a gift card provided as a reward or invalidate the reward in the next contract year after the enrollee has completed the target activity. We believe that this is an important beneficiary protection to ensure that rewards are timely provided to the enrollee and that the enrollee retain the rights to use the reward whenever he or she wants. (85 FR 9107) While we acknowledge that the preamble explanation introduced the idea of "timely provision to the enrollee," that was not part of the proposed regulation text. Our regulatory text was intended to require that the reward item be provided to the enrollee, such as through transfer of ownership or

delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year. The intended criterion was that the reward-item be delivered based on a target activity completed in the contract year during which this R&I program was offered.

We are finalizing paragraph (d)(2)(ii) with modifications such that the regulation requires delivery based on the completion of the target activity during the contract year. Under this final rule, delivery of the reward item in the next contract year, such as after administrative activities associated with the reward program are performed, is permissible. However, the qualifying individual cannot be required to continue activities into the next contract year to retain or gain the reward earned during a prior contract year.

Reward Items. At § 422.134(d)(2)(i), we proposed to reorganize existing provisions and codify existing guidance to set forth clearer regulation text about what items could not be offered as rewards. Currently, § 422.134(c)(2) prohibits rewards from being offered in the form of cash or monetary rebates and our subregulatory guidance explains that this includes reductions in cost sharing or premiums and gift cards that are redeemable for cash. We proposed regulation text explicitly to prohibit reward items from being offered in the form of cash, cash equivalent or other monetary rebates (including reduced cost sharing or premiums). We also proposed regulation text to set forth that an item is considered cash or cash equivalent if it: (A) Is convertible to cash (such as a check); or (B) Can be used like cash (such as a general purpose debit card). In addition, the proposed rule prohibited reward items that involve elements of chance or have a value that exceeds the value of the target activity itself.

We also proposed, at paragraph (d)(3), to list examples of permissible reward items for a target activity, specifically that reward items may: (i) consist of "points" or "tokens" that can be used to acquire tangible items; and (ii) be offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services. Like the

prohibition on using items that involve an element of chance, the examples of permissible reward items were based on our guidance and responses to questions since § 422.134 was first adopted.

Comment: We received many comments on these provisions. Commenters advocated for authority to use general debit cards as a reward item, specifically arguing that targeted gift cards can be burdensome and confusing. A commenter advocated for the provision of incentives in the form of monetary credits toward monthly premiums or cost sharing requirements.

Response: Section 1851(h)(4) and 1854(d)(1) of the Act both prohibit an MA organization from giving enrollees cash or monetary rebates as an inducement for enrollment *or otherwise*. Since the statute prohibits cash or monetary rebates, we proposed, consistent with the statute, to prohibit reductions in cost-sharing from being used as a reward. Since the statute prohibits cash, we proposed to prohibit giving a reward for anything that can be used as cash or cash equivalent such as checks or general debit cards. In arriving at this conclusion, we saw the primary attribute of cash as its universal use to purchase. For this reason, we proposed to prohibit general debit cards which can be used universally but to allow, at paragraph (d)(3)(ii), a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services. We similarly prohibited checks which are easily converted to cash and then can be used universally.

As to the suggestion that using that targeted gift cards can be burdensome and confusing and therefore CMS should permit the use of general debit cards as rewards, we note that the use of any gift card as a reward item is optional. If a plan finds that beneficiaries are confused or burdened by targeted gift cards, the MA plan may choose to use another form of reward. As explained above, we view general debit cards as the equivalent of cash and believe that § 422.134 must be consistent with the statutory prohibition on MA organizations providing cash as an inducement.. Our experience with the program suggests that many stakeholders implement R&I with multiple gift cards. While it would be more convenient to have just one gift card, we do not believe it correct to say that multiple gift cards are burdensome and cumbersome since in

practice plans are already using this vehicle for rewards, implying that their enrollees find the benefits of multiple gift cards outweigh the burdensomeness. As to the minor inconvenience of multiple gift cards, minor inconvenience is not a sufficient reason to override a statutory prohibition. Further, we note that providing a choice among equal value gift cards, so long as all qualifying individuals are offered the identical choice consistent with § 422.134(d)(1)(i) as finalized here, is also permitted.

We are finalizing these provisions as proposed for the reasons outlined in the proposed rule and our responses to comments.

Marketing. As part of the reorganization of § 422.134, we proposed at paragraph (e) a provision requiring compliance with all marketing and communications requirements in Part 422, Subpart V rather than specifically adopting marketing and communication requirements for reward programs in § 422.134. Section VI.H of the proposed rule and section V.E of this final rule discuss the marketing and communications requirements for MA organizations, including provisions specific to reward programs.

Comment: Commenters expressed concern that while CMS has proposed that R&I programs be subject to the marketing requirements, they are only communications and not subject to marketing requirements.

Response: As proposed (and finalized) in § 422.134(g)(3), and as indicated in CMS' subregulatory guidance in Chapter 4, R&I are classified as non-benefits. Consequently, R&I are not subject to inclusion in the Annual Notice of Change (ANOC) or Evidence of Coverage (EOC). Nevertheless, CMS believes treating materials about R&I programs offered by MA plans as subject to the marketing and communications requirements and standards in Part 422, Subpart V is appropriate. As proposed and finalized in Section V.E of this final rule, the definition of marketing (§§ 422.2260 and 423.2260) includes content regarding rewards and incentives; we believe that this is appropriate because the availability of R&I programs and rewards may influence the decision of a beneficiary to enroll or stay enrolled in a particular MA plan. The

beneficiary protections, review standards and prohibitions that apply to marketing materials and activities (as well as those that apply to communications) will apply to materials and activities about rewards and incentives when those materials and activities are intended to (i) draw a beneficiary's attention to an MA plan or plans or (ii) influence a beneficiary's enrollment decision(s). We also direct readers to section V.E of this final rule for additional discussion of the definition of marketing and the standards and requirements that apply to marketing and communications materials.

We are finalizing paragraph (e) as proposed for the reasons outlined in the proposed rule and our responses to comments.

Reporting requirements. At § 422.134(f), we proposed regulation text to require an MA organization to make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

Comment: We received comments on this proposal. A commenter supported a reporting requirement to ensure that plans are implementing any reward programs fairly and without discrimination. Another commenter believed it sufficient for the purpose of monitoring and oversight that MAOs provide information upon request without the additional burden of a specific reporting format.

Response: We thank the commenters for their interest in oversight and fairness and support for a reporting requirement. Currently, § 422.134(c)(3) includes a reporting requirement in connection with R&I programs and our proposal carried over that provision verbatim to the proposed revision at 422.134(f). The policy itself was not originally proposed in this rulemaking; what is finalized in this rule is the change of location from paragraph (c)(3) to paragraph (f). Based on the current regulation, CMS has had for several years annual reporting requirements for R&I programs. These reporting requirements are accessible at

https://www.cms.gov/files/document/cy2020-part-c-reporting-requirements04222020.pdf. Thus far, CMS has found these reporting requirements sufficient for its oversight needs.

Miscellaneous. At § 422.134(g)(2), we proposed regulation text to clarify that plan failure to comply with R&I program requirements may result in a violation of one or more of the bases for imposing sanctions at § 422.752(a). At § 422.134(g)(3), we proposed regulation text to codify existing guidance that the reward and incentive program is classified as a non-benefit expense in the plan bid and that disputes on rewards and incentives must be treated as a grievance under 422.564.

Comment: A few commenters supported our codification at paragraph (g)(3) that R&I programs are classified as a non-benefit expense.

Response: We thank the commenters for their supportive comments.

We received no other comments on these provisions and are finalizing as proposed for the reasons provided in the proposed rule.

Midyear changes. At § 422.134(g)(4), we proposed regulation text to prohibit mid-year changes to reward and incentive programs. We explained in the proposed rule that this new provision was based on how the reward and incentive program must be included in the plan bid each year and that we considered it an important beneficiary protection.

Comment: We received numerous comments with diverse perspectives on our proposal to prohibit mid-year changes in R&I programs. Some commenters were supportive: They were aware of the issue of the integrity of the bid and also believed that mid-year R&I program changes would be confusing to enrollees. By contrast, some commenters wanted the flexibility to respond mid-year to low utilization of plan resources and benefits by designing rewards targeted to those populations. Other commenters suggested a compromise: Allow additions of R&I mid-year (positive changes) but prohibit negative changes (removal of R&I).

Response: We thank all commenters for their insights. In reviewing these comments, we also considered that reward and incentives are not classified as benefits and therefore are not

subject to the same prohibition on mid-year changes in benefits that we adopted in 2008 (73 FR 43628). Historically, we have permitted changes in administrative rules or policies for other things that are not benefits; non-benefit changes midyear are governed by the requirements relating to mid-year plan rule changes presented at 42 CFR 422.111(d), which ensures that enrollees are notified of the changes at least 30 days before the effective date of the change. We believe that these considerations resolve the concerns underlying our proposal to prohibit mid-year changes in reward and incentive programs. Consequently, we are not finalizing the proposed regulatory change to prohibit midyear changes to R&I.

After consideration of the comments we received on proposed § 422.134 and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed regulation with some limited changes from the proposal. Specifically, we are finalizing minor technical and grammatical changes throughout the regulation and several substantive changes. The substantive changes include: (1) changes in the codification and application of the uniformity and accommodation policies finalized in paragraphs (c)(1)(iv) and (v) but that were proposed in paragraphs (c)(2)(ii)(A) and (B); (2) clarifying changes in paragraph (d)(1)(i) regarding how all qualifying individuals must be offered the same rewards for the particular target activity; (3) clarifying changes in the definition of qualifying individual; and (4) clarifying changes in paragraph (d)(1)(iii) to address delivery of a reward. In addition, we are not finalizing paragraph (g)(4). Because § 422.134 as finalized here substantially reorganizes the existing regulation while maintaining most of the current requirements, Table E6 summarizes where existing provisions have been moved and where we are codifying existing guidance.

TABLE E6: COMPARISON OF FINALIZED CFR REGULATIONS WITH CURRENT CFR REGULATIONS

§ 422.134, CMS-4190-F2 (As finalized)	Brief Summary	Current Provision
(a) Definitions	Provide definitions of R&I, reward item, target activity etc.	Codifies terms and concepts used in the regulation consistent with current guidance.
(b) Offering an R&I program	Plans may offer an R&I Program	Current 422.134(a)
(c) Target Activities	One comprehensive list of all requirements and prohibitions (Details are provided in the following rows)	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(c)(1)	Requires that the level of completion of the target activity be specified	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(c)(1)(i)	Specifies that the target activity must directly involve the qualifying individual	Codifies existing guidance
(c)(1)(ii)	The target activity must be specified, in detail, as to the level of completion needed in order to qualify for the reward item	Clarification and restatement of current § 422.134(c)(1)(i) and codifies existing guidance
(c)(1)(iii)	The target activity must be health related	Currently §422.134(a) and in existing guidance
(c)(1)(iv)	The target activity is required to be uniformly offered to all qualifying enrollees	Current § 422.134(b)(2)
(c) (1) (v)	Accommodations are required for those unable to do the target activity but otherwise qualify	Codifies existing guidance related to the non-discrimination requirement in current § 422.134(1)(1)(ii)
(c)(2)	Prohibitions on target activities	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(c)(2)(i)	The target activity shall not be related to Part D benefits	Codifies existing guidance and the interpretation adopted in the 2014 final rule
(c)(2)(ii)	The target activity shall not be discriminatory	Current § 422.134(b)(1) prohibits discrimination in the R&I program generally
(c)(2)(ii)(A)	Not reward a health status measurement	Codifies existing guidance

		related to the non-discrimination requirement in current § 422.134(1)(1)(ii)
(d) Reward items	List of requirements, prohibitions, and permissions	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(d)(1)	Requirements that must be met for reward items	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(d)(1)(i)	Reward items must be identically offered to all qualifying enrollees completing the target activity	Current § 422.134(b)(2) and codifies current guidance
(d)(1)(ii)	Reward is direct and tangible	Codifies existing guidance
(d)(1)(iii)	Ownership transfer of reward items for target activities completed within the contract year during which this R&I program was offered	Codifies and clarifies existing guidance
(d)(2)	Prohibitions on reward items	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(d)(2)(i)	Prohibition of cash and monetary rebates	Current § 422.134(c)(2)(i)
(d)(2)(i)(A) and (B)	Definition of cash, cash equivalents or other monetary rebates.	New provision to clarify terms
(d)(2)(ii)	Value of reward item does not exceed value of target activity	Current § 422.14(c)(1)(iii)
(d)(3)	Reward not based on elements of chance	Codifies existing guidance
(d)(3)	Allowance of i) tokens and ii) specified gift cards	Codifies existing guidance
(e) Marketing Requirements	Makes marketing requirements as found in Subpart V of 42 CFR 422 applicable to this section 422.134.	Current § 422.134(c)(2)(ii) prohibits targeting new enrollees; marketing requirements are otherwise not in current § 422.134
(f) R&I Disclosure	Disclose information and provide reports on request to CMS	Current § 422.134(c)(3)
(g) Miscellaneous	Items not directly about requirements of reward item, target activity, marketing, or disclosure	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance
(g)(1)	Compliance with other laws (anti-kickback, fraud, etc.)	Current § 422.134 (c)(1)(iv)
(g)(2)	Possible sanctions for violation	Current § 422.134(b)(3)
(g)(3)	Non-benefit expense in bid	Codifies current guidance

		about application of bidding regulations at §§ 422.254 and 422.256

E. Requirements for Medicare Communications and Marketing (§§ 422.2260 – 422.2274; 423.2260 – 423.2274)

Sections 1851(h) and (j) of the Act provide a structural framework for how Medicare Advantage (MA) organizations may market to beneficiaries and direct CMS to adopt standards related to the review of marketing materials and limitations on marketing activities. Section 1860D-1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) for approval of marketing material and application forms for Part D plan sponsors. Section 1860D-4(*l*) of the Act applies certain prohibitions under section 1851(h) to Part D sponsors in the same manner as such provisions apply to MA organizations. CMS has adopted regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in § 422.111; 42 CFR part 422, Subpart V; § 423.128; and 42 CFR part 423, Subpart V; these regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under § 417.428, most marketing requirements in Subpart V of part 422 apply also to section 1876 cost plans. CMS has long provided further interpretation and guidance for these regulations in the form of a marketing manual titled the Medicare Communications & Marketing Guidelines (MCMG), previously known as the Medicare Marketing Guidelines. Because the proposal and this final rule are applicable to MA organizations, Part D plan sponsors, and cost plans, we refer to each of these regulated entities as a "plan."

In the February 2020 proposed rule, CMS proposed to codify guidance contained in the MCMG by integrating it with the existing regulations. To incorporate the guidance, we proposed to reorganize and redesignate the existing and proposed provisions according to the topics included in the MCMG; we explained that this order and organization was familiar to the

Medicare Advantage, cost, and Part D plans that are subject to the rules. As a result, the proposed regulatory provisions reflected some changes to the current regulations, even though CMS did not propose to substantively change much of the policy. To be clear, the policies we proposed to codify are not new; they are in the MCMG and were developed over time in concurrence with stakeholder feedback to implement and administer the current regulations.

The first of the policies that CMS proposed to codify, in §§ 422.2260 and 423.2260, is the guidance related to the definitions of "marketing" and "communications," as well as additional definitions from the MCMG. As explained in the February 2020 proposed rule, CMS has amended the marketing regulations for both the MA and the Part D programs at 42 CFR parts 422 and 423, subparts V, respectively, since their original implementation, and provided sub-regulatory guidance in the MCMG each time to ensure beneficiaries receive the necessary information to make informed choices. Recently, in the April 2018 final rule, we established new definitions for communications materials and activities and marketing materials and activities in 42 CFR §§ 422.2260 and 423.2260, which set out the scope of materials and activities subject to the regulations. In the 2019 MCMG, we clarified these definitions based on our interpretation of the regulatory terms "intent" and "content" as the deciding factors for when a communication activity or material is marketing.

We proposed to codify the MCMG guidance and revise the regulation text at §§ 422.2260 and 423.2260 to align more closely with the interpretation explained in our guidance. Specifically, we proposed that "marketing" means communications materials and activities that meet certain standards for intent and content that were enumerated in the proposed regulation text. For the *intent* standard, we proposed the same intent language that is in the current regulation, with a technical change to separately list out two different intent standards (paragraphs (1)(i)(B) and (C) in the proposed definition of marketing) that are in one paragraph (paragraph (3)) in the current definition of marketing at §§ 422.2260 and 423.2260. We note that a typographical error appeared in the description of this technical change in the preamble to the

February 2020 proposed rule, which incorrectly stated that the two separate intent standards described here appeared at paragraphs (1)(ii) and (iii) of the proposed rule's definition of marketing (whereas this text actually appeared in paragraphs (1)(i)(B) and (C) of the proposed rule), and that these standards appear in one paragraph (paragraph (3)) of the current definition of marketing materials at §§ 422.2260 and 423.2260 (whereas these standards currently appear in paragraph (3) of the current definition of marketing in the same regulations). We explained in the February 2020 proposed rule that, when evaluating the intent of an activity or material, we intended, consistent with our current practice and guidance, to consider objective and contextual information (for example, audience, timing, etc.) in applying the proposed definition. Under our proposal, CMS would not be limited by the plan's statements about its intent.

In the content standard, we proposed that the regulation state affirmatively what must be included for a communications activity or material to be a marketing activity or material, rather than stating what is excluded (as the current regulation does). We explained that the first two types of content listed (paragraphs (2)(i) and (ii)) in the proposed definition of marketing are derived from the current regulation (although we explained that "premiums" was also included, consistent with the MCMG). We proposed to codify a third type of content in the definition (information on rewards and incentives programs), as we wanted to be clear that while rewards and incentives themselves are not a benefit, they are used as a means of prompting a beneficiary to use a specific benefit, and therefore our policy has been that information on rewards and incentives fall within the definition of marketing. We explained that our proposal would avoid any confusion and ensure that plans continue to be aware that when providing any information on rewards and incentives, they must follow the same requirements as for other marketing. We also proposed to streamline the definitions by removing the list in the current regulation of examples of materials (for example, brochures or posters) and explained that we did not believe this list of examples is necessary, as we evaluate whether a material is marketing based on intent and content rather than its particular form. Additionally, we proposed to combine the definitions

for "communications" and "communications materials," as well as "marketing" and "marketing materials" to streamline the definitions section. We also explained that this would be consistent with how we have interpreted the current regulations that both activities and materials are subject to the same intent and content standards. We also proposed that the regulatory definition of "communications" state that communications activities and use of materials are those "created or administered by the MA organization or any downstream entity."

Finally, we proposed to codify at §§ 422.2260 and 423.2260 additional definitions that apply to plan marketing. Specifically, we proposed to add definitions of "advertisement (ad)," "alternate format," "banner," "banner-like advertisements," and "Outdoor Advertising (ODA)." We explained that these familiar terms have been defined and used throughout the MCMG. Our proposed definitions of these terms included some technical and clean-up edits but were substantively consistent with current policy and guidance. We explained that in codifying much of the MCMG, we believed it was paramount that we codify these definitions which are used throughout the MCMG and in our proposed regulations.

We next proposed to codify, at §§ 422.2261 and 423.2261, requirements for plans to submit certain materials to CMS for review, the process for CMS review, and the standards by which CMS will perform the review. These requirements are currently found in §§ 422.2262, 422.2264, 423.2622, and 423.2264, as well as in section 90 of the MCMG, which builds upon those sections and includes detailed operational instructions to plans regarding submission, review, and distribution of marketing materials (including election forms). In particular, we proposed at §§ 422.2261(a)(1) and 423.2261(a)(1) that the Health Plan Management System (HPMS) would be the primary system of record and the mechanism by which CMS would collect and store submitted plan materials for review and evaluation. Additionally, we proposed to codify, at §§ 422.2261(a)(2) and 423.2261(a)(2), our current policy that only plans can submit materials to CMS for review and approval for use and to specify that this policy prohibits third parties/downstream entities from submitting materials directly to CMS. Additionally, in new

§§ 422.2261(d) and 423.2261(d), we proposed to codify that CMS would review submitted materials for compliance with all applicable requirements in §§ 422.2260 through 422.2267 and §§ 423.2260 through 423.2267 and that the benefit and cost information accurately reflects the plan's bid. We explained the proposed standards are consistent with our current policy and how we review marketing materials.

We next proposed to codify general standards for plan communications, including requirements related to product endorsements and testimonials and standardization of certain materials (specifically, certain telephone numbers and material IDs) at §§ 422.2262 and 423.2262. These standards are currently found in §§ 422.2268(a) and 423.2268(a), which also include examples of what plans may not do. While the proposed regulations included the current general standards prohibiting MA plans from misleading, confusing, or providing inaccurate information to current or potential enrollees, we proposed to include additional examples of what plans may not do (in paragraph (a)(1)) and to incorporate examples of what plans may do (in paragraph (a)(2)), consistent with section 30 of the MCMG.

We also proposed to codify, at §§ 422.2262(b)(2) and 423.2262(b)(2), requirements regarding endorsements and testimonials that are in the policy currently found in section 30.8 of the MCMG. We proposed in §§ 422.2262(b)(1) and 423.2262(b)(1) that, consistent with our current policy, product endorsements and testimonials may take different forms. We also proposed to codify at §§ 422.2262(c) and 423.2262(c) requirements currently found in section 30 of the MCMG related to including telephone numbers (specifically, customer service numbers and 1-800-MEDICARE) in materials. We explained that these additional parameters for how telephone numbers are communicated in communications and marketing ensure that beneficiaries get useful and accurate information. Finally, we proposed to codify at §§ 422.2262(d) and 423.2262(d) requirements related to standardized material identification, currently found in section 90.1 of the MCMG.

We proposed to codify at §§ 422.2263 and 423.2263 requirements related to how plans may conduct marketing, which is specified as a subset of communications and therefore also subject to the requirements proposed in §§ 422.2262 and 423.2262. First, we proposed to clarify, at §§ 422.2263(a) and 423.2263(a), that October 1 is the date plans may begin marketing for the upcoming plan year. This is consistent with longstanding guidance, but the current rule lacks specificity and context. We also proposed to codify at §§ 422.2263(b) and 423.2263(b) examples of what plans may not do in marketing. As explained in the February 2020 proposed rule, this list reflects current policy in existing §§ 422.2268(b), 423.2268(b) and section 40.1 of the MCMG, with some technical edits. As our proposal was to codify all current requirements and guidance on marketing and communications, we explained that a number of the prohibitions that are currently stated in §§ 422.2268(b) and 423.2268(b) would be codified elsewhere in our proposed regulations, where the provisions would topically belong under the new regulatory structure. Although not discussed in the preamble to the February 2020 proposed rule, §§ 422.2263(b)(2) and 423.2263(b)(2) included a provision specific to the prohibition on providing gifts unless they are of a nominal value; the proposed regulation provided that we would defer to guidance from the HHS Office of the Inspector General (OIG) to determine what dollar threshold to use to determine if a gift is of nominal value. Under current CMS guidance in the MCMG, section 40.4 applies the current regulation prohibiting gifts other than nominal gifts to set a cost threshold of $15 per gift and $75 aggregated, per person per year, which are the amounts that the HHS OIG identified as nominal amounts in its current applicable guidance, dated December 7, 2016 and available on-line here: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2006053221-hi-oigpolicystatementgiftsofnominalvalue.pdf. Proposed §§ 422.2263(b)(2) and 423.2263(b)(2) provided that a determination of nominal value would be governed by guidance published by the HHS OIG in order for §§ 422.2263(b)(2) and 423.2263(b)(2) to remain in alignment with OIG guidance and policy about nominal gifts going forward. We note here that achieving alignment on this issue provides clearer and more

consistent direction from the government to regulated plans and provider greater consistency in overall monitoring and enforcement. Finally, at § 422.2263(c), we proposed to codify requirements related to marketing of Star Ratings currently located in section 40.6 of the MCMG.

We next proposed to codify, at 42 CFR 422.2264 and 423.2264, requirements related to plan contact with Medicare beneficiaries and a beneficiary's caregivers. Our proposed regulation text used the term "beneficiary contact" to include all outreach activities to a beneficiary or a beneficiary's caregivers by the plan or its agents and brokers. First, in 42 CFR 422.2264(a)(1) and 423.2264(a)(1), we proposed to codify the policy for when unsolicited contact is permitted, including direct mail and email which are currently found in the MCMG. Under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we proposed to codify the rules for when unsolicited direct contact with beneficiaries is and is not permitted. Currently, §§ 422.2268(b)(13) and 423.2268(b)(13) explicitly prohibit plans from soliciting door-to-door or engaging in other unsolicited contact and our guidance in section 40.2 of the MCMG applies and interprets this prohibition in specific contexts, with additional detail about activities we consider (and do not consider) unsolicited contact. Additionally, under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we also proposed to codify the current policy that unsolicited direct messages from social media platforms are also prohibited, as currently addressed in section 30.6 of the MCMG. We also proposed to clarify that plans may contact their current members (including those individuals enrolled in commercial plans who are becoming eligible for Medicare) regarding plan business, which is consistent with our current policy in the MCMG in section 40.3. Finally, in §§ 422.2264(c) and 423.2264(c), we proposed to codify requirements regarding events (such as meetings) with beneficiaries, currently found in section 50 of the MCMG. As explained in the February 2020 proposed rule, the proposed regulation text included specific provisions that are consistent with our current policies of what plans may do. Our proposed revisions to §§ 422.2267 and 423.2267 would incorporate the policy currently in §§ 422.2264 and 423.2264,

"Guidelines for CMS Review," with more detail. We explained that whereas the current §§ 422.2264 and 423.2264 provide general guidance on important information that plans must provide to a beneficiary interested in enrolling, proposed §§ 422.2267 and 423.2267 would include more detailed standards and requirements on the specific materials or content that a plan must produce. The proposed rule explained that, collectively, the required materials and content outlined in proposed §§ 422.2267 and 423.2267 account for the requirements in the current §§ 422.2264 and 423.2264.

We next proposed to codify requirements for plan websites at new §§ 422.2265 and 423.2265. As explained in the February 2020 proposed rule, the current regulations at §§ 422.111(h)(2) and 423.128(d)(2) establish the requirement for Part C and Part D plans to have an internet website and include requirements regarding content that must be posted on the website and the MCMG has historically provided additional detail on required website content, including the dates by which plan content was required to be posted annually. Proposed §§ 422.2265 and 423.2265 would restate the requirement to have a website and codify the additional requirements and guidance currently in section 70 of the MCMG.

We next proposed to codify at §§ 422.2266 and 423.2266 requirements plans must follow for activities in a healthcare setting, including requirements for provider-initiated activities, plan-initiated provider activities, and plan activities. We explained that proposed §§ 422.2266 and 423.2266 would include requirements currently located in §§ 422.2268(b)(7) and 423.2268(b)(7) and codify policies interpreting those requirements in section 60 of the MCMG.

We next proposed to codify, at new §§ 422.2267 and 423.2267, instructions for how plans should submit required materials to CMS for review. Specifically, we proposed to codify the guidance for standardizing and monitoring the production of required documents, including a listing of these required documents, currently found in section 100 and Appendices 2, 3, 4, and 5 of the MCMG. As we explained in the February 2020 proposed rule, some of these required materials are addressed in current regulations (for example, the Annual Notice of Change

(ANOC) and the Evidence of Coverage (EOC)) while others are only described in the MCMG (for example, the Summary of Benefits (SB)). Therefore, we proposed to specify all of the required materials and content in §§ 422.2267(e) and 423.2267(e). In doing so, we refer to current established regulatory authority when relevant. We did not propose any changes to §§ 422.2272 and 423.2272, which address licensure of marketing representatives and confirmation of marketing resources.

Finally, we proposed to consolidate, at §§ 422.2274 and 423.2274, requirements related to plan compensation to agents, brokers and other third parties currently found at §§ 422.2272, 422.2274, 423.2272, and 423.2274, and section 110 of the MCMG. We explained in the February 2020 proposed rule how our proposed revised and consolidated text generally would not change the policies currently laid out in the existing regulations and guidance, but that significant technical and organizational edits were used to improve clarity and reduce duplication in the proposed regulation text. We proposed to codify our method for calculating fair market value for agent/broker compensation, as current regulations limit compensation to fair market value but do not further define it or provide the methodology CMS uses for calculating it. As we explained in the February 2020 proposed rule, CMS first developed the Fair Market Value (FMV) calculation used for regulating plan compensation paid to agents and brokers for contract year 2009 and published these rates in an HPMS memo on December 24, 2008. To develop the FMV, we requested that plans submit the fees they paid in 2006 and 2007, as well those planned for 2009; plans submitted approximately 19,000 records that we analyzed based on geographic location and organization type. Following this analysis, we developed the FMV for MA plans, 1876 cost plans and Part D plans. The MA FMV rates for enrolling a single beneficiary were established at a national rate of $400, with exceptions for Connecticut, Pennsylvania, and DC ($450), and California and New Jersey ($500), based on higher rates being reported in those geographic areas. The PDP rate was set at $50 for a single enrollment nationally. For years after contract year 2009, we calculated the FMV based on the National Per Capita MA Growth Rate

for aged and disabled beneficiaries for Part C and 1876 Cost plans and the Annual Percentage Increase for Part D, using the following formula: Current Year FMV + (Current Year FMV * National Per Capita MA Growth Rate for aged and disabled beneficiaries) for MA and 1876 cost plans and Current Year FMV + (Current Year FMV * Annual Percentage Increase for Part D) for PDP plans. Our proposal for §§ 422.2274 and 423.2274 would codify a definition of FMV with this formula. Based on this formula, the FMV for 2022 would be the FMV for CY 2021 + (CY2021 FMV * National Per Capita Growth Rate for aged and disabled beneficiaries). We issued an HPMS memo on May 29, 2020 with the FMV amounts for 2021. For CY2021, the FMV rates for MA and 1876 Cost Plans are: National FMV is $539, FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, FMV for California and New Jersey is $672 and the FMV for U.S. Virgin Islands and Puerto Rico is $370. For CY2021, the FMV rate for all Prescription Drug Plans is $81.

Additionally, we noted that section 110.7.1 of the MCMG currently clarifies when the regulations at §§ 422.2274(b)(2) and 423.2274(b)(2), which require recovery of agent compensation when a newly-enrolled individual disenrolls within the first 3 months of enrollment (rapid disenrollment), do not apply. We proposed to codify that guidance at §§ 422.2274 and 423.2274; although the preamble of the February 2020 proposed rule identified this policy as being codified in proposed paragraph (g)(2)(ii)(C), our proposed regulation text addressed exceptions to the requirement for plans to recover agent compensation at paragraph (d)(5)(iii). In addition, we refer readers to section IV.C. of this final rule, which addresses our proposal regarding referral and finder's fees for agents and brokers.

In summary, our proposal was for new and revised regulatory sections in Subpart V as follows:

- Sections 422.2260 and 423.2260 revise and streamline the current definitions of "communications" and "marketing," and codify definitions for additional key terms from the MCMG used throughout the proposed regulations.

• Sections 422.2261 and 423.2261 contain requirements for plans to submit certain materials to CMS for review, the process for CMS review and the standards by which CMS will perform the review, taken from current §§ 422.2262, 422.2264, 423.2622, and 423.2264 and section 90 of the MCMG.

• Sections 422.2262 and 423.2262 specify the general standards for plan communications materials and activities, including endorsements and testimonials, and examples of what plans may and may not do. These sections also contain requirements related to standardization of certain key elements of communications materials (specifically, telephone numbers and material IDs). These sections include policies currently articulated in current §§ 422.2268 and 423.2268, as well as sections 30 and 90.1 of the MCMG.

• Sections 422.2263 and 423.2263 contain requirements for how plans must conduct marketing. These sections will incorporate requirements currently in §§ 422.2268 and 423.2268, as well as additional guidance from section 40 of the MCMG.

• Sections 422.2264 and 423.2264 address the rules for plan contact with Medicare beneficiaries. These sections include requirements and standards currently in §§ 422.2268 and 423.2268, and further expanded upon in sections 40 and 50 of the MCMG.

• Sections 422.2265 and 423.2265 explain the requirements for plans to have a website as well as what must, may, and must not be on the website. These sections include material currently in section 70 of the MCMG.

• Sections 422.2266 and 423.2266 contain the requirements plans must follow for activities in a healthcare setting. These sections include material from current §§ 422.2268 and 423.2268, and from section 60 of the MCMG.

• Sections 422.2267 and 423.2267 provide instructions on materials and content that CMS requires plans to deliver or make available to beneficiaries, including required disclaimers. These sections include material from section 100 and Appendices 2, 3, 4, and 5 of the MCMG.

• Sections 422.2274 and 423.2274 consolidate requirements from §§ 422.2272, 422.2274, 423.2272, and 423.2274, and section 110 of the MCMG regarding agents, brokers, and compensation to third parties.

Finally, we requested comment on how CMS should implement prohibitions related to plan marketing during the open enrollment period (OEP). Section 1851(e)(2)(G)(iv) of the Act, as added by section 17005 of the Cures Act, prohibits marketing during the open enrollment period (OEP). The current regulations implementing the statutory prohibition on plan marketing during the OEP are at §§ 422.2268(b)(10) and 423.2268(b)(10). We explained in the February 2020 proposed rule that the MCMG includes additional guidance about what activities fall within this prohibition including, specifically, that plans are prohibited from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period (AEP), and leveraging agent/broker activities that target the OEP as a way to make further sales.

We received the following comments on our proposal and our responses follow:

Comment: Several commenters expressed support for CMS codifying the various requirements traditionally found in the MCMG. Many of these commenters questioned if CMS still intended to produce an MCMG after these regulations are adopted as final. Similarly, other commenters specifically requested that CMS continue to produce the MCMG in tandem with the requirements found in the final rule.

Response: CMS appreciates the favorable response to the codification of the many requirements typically found in the MCMG. While the agency believes it would be duplicative to continue to produce the MCMG in its current form, we do intend to continue producing sub-regulatory guidance to provide operational instruction to plans. We believe that the regulations we are finalizing in parts 422 and 423, subparts V are clear and succinct.

Comment: A commenter expressed concern that beneficiaries could be negatively impacted by CMS's decision to stop collecting co-branded relationship data in the Health Plan Management System (HPMS).

Response: CMS notes that the decision to no longer collect this data through the HPMS Marketing Module predates this rulemaking. Although CMS no longer collects co-branding information through the HPMS Marketing Module, the co-branding relationship data is collected elsewhere in HPMS, making the need to collect it twice in one system duplicative. In addition, plans continue to be responsible for all materials and activities, including those that they create or carry out in conjunction with any co-branded entities. All regulatory requirements pertaining to communications and marketing still apply to co-branded materials, including the requirement to submit all marketing materials to CMS. As a result, we do not believe that the negative impact on beneficiaries as contemplated by the commenter is likely.

Comment: A commenter suggested that CMS eliminate the requirement that plans and sponsors prorate agent/broker commissions. The commenter noted the amount of work to enroll an individual does not change if the enrollment takes place in November or in January, so the requirements related to prorating payments do not make sense and are unfair to Medicare-certified health insurance agents.

Response: CMS thanks the commenter for their input. Prorated payments of agent/broker commissions are a necessary component of the compensation requirements finalized in this rule because we believe that providing a full year payment to an agent, rather than a prorated amount, might incentivize agents and brokers to encourage beneficiaries to switch plans during the coverage year in order for the agent or broker to receive a full year of compensation, thus resulting in the unnecessary churning of beneficiaries from one plan to another. Section 1851(j)(2)(D) of the Act specifically directs the Secretary to establish limitations on compensation for agents and brokers to ensure payments create incentives for agents and brokers to enroll beneficiaries into the plan that best meets the beneficiary's needs. Providing a prorated

amount incentivizes the agent or broker to find the plan that is the best fit for the beneficiary so that the beneficiary will remain enrolled throughout the year, rather than changing plans due to dissatisfaction with the coverage or feeling as though they were misled. The prorated compensation also provides an incentive for the agent or broker to continue to service the beneficiary's needs after the sale.

Comment: A commenter was in favor of CMS codifying the rules for agent/broker compensation, noting that the transparency is helpful for plans as well as agents and brokers.

Response: CMS appreciates the comment.

Comment: A few comments suggested that CMS provide more examples of specific materials that would fall under the definition of communication or marketing in §§ 422.2260 and 423.2260 of the regulation.

Response: CMS understands that examples can aid plans in better understanding the definitions of communications and marketing, but we do not believe that including examples in the regulation text are the best manner in which to achieve this objective. Given the more static structure of regulations as compared to the dynamic nature of communications and marketing, we believe that sub-regulatory guidance and training is the more appropriate manner by which to apply the regulatory definitions and standards to particular facts in order to identify and convey our requirements. With the finalization of the proposed amendments to §§ 422.2260 and 423.2260, CMS will gauge need for examples and provide them as required. With that said, we note the definitions codified in this final rule are consistent with our current practice and the current regulations, as we discussed in the February 2020 proposed rule; therefore the examples in section 20.1 of the MCMG dated September 5, 2018, and available online here: https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf, remain applicable. In addition, we note that the extensive list of standardized and model materials in §§ 422.2267(e) and

423.2267(e) generally specifies which materials are communication materials and which are marketing materials.

Comment: A commenter suggested that definitions in §§ 422.2260 and 423.2260 such as "alternate format," "banner," "banner-like advertisements," and "outdoor advertising" should be considered marketing activities because these types of materials are also evaluated on intent and content and not on their particular form.

Response: We agree that "alternate format," "banner," "banner-like advertisements," and "outdoor advertising" are evaluated based on their intent and content. We clarify, however, that such materials are not automatically considered marketing under the definitions we proposed and are finalizing here at §§ 422.2260 and 423.2260, as specific materials in these formats could meet either the definition of communications or of marketing based on their intent and content. For example, a billboard (outdoor advertising) that says "Super Medicare Advantage – a new choice in Medicare for 2022" is not marketing as it does not include or address the content outlined in paragraph (2) of the definition of "marketing" under §§ 422.2260 and 423.2260. Based on the possibility of these items being communications or marketing depending on the particular facts or circumstances, CMS is not changing the definitions.

Comment: A commenter suggested that CMS should consider establishing a separate pre-release review process for communications, given their importance for beneficiaries. The commenter specifically cited CMS required materials that are communications. The commenter strongly urged that in cases where CMS identifies inaccuracies or misleading information through a post-release review, CMS allow affected beneficiaries to have a special enrollment period, in order to mitigate consequences of decisions based on inaccurate or misleading information.

Response: We agree that appropriate oversight of communication materials is an important beneficiary protection. We believe that our current oversight processes ensure the appropriate level of beneficiary protection. CMS currently collects certain CMS required

materials, such as the Evidence of Coverage making them subject to retrospective reviews. In addition, CMS reviews the accuracy of CMS required materials outside of the formal material submission process, for example provider directory reviews have been conducted outside of the formal HPMS material submission process for several years.

In this final rule, CMS is also maintaining authority (currently in §§ 422.2262(d) and 423.2262(d) and codified here at §§ 422.2261(c)(1) and 423.2261(c)(1)) to collect, prior to use by plans, certain designated communications materials that are critical to beneficiaries and plan enrollees understanding plan options or accessing their benefits; the final regulation text provides an example of a communications material that meets this standard: the Evidence of Coverage (EOC). CMS may also retrospectively collect any communications materials for subsequent review under §§ 422.504(f)(2)(vii) and 423.505(f)(2)(viii). In addition, CMS can collect data on communications materials through beneficiary complaints, and communication and marketing surveillance activities. In this final rule, we have included §§ 422.2261(c)(2) and 423.2261(c)(2) to ensure that CMS has the authority to require additional communications materials be submitted, or submitted and reviewed, prior to use based identified as a concern based on errors identified through the methods outlined above.

These regulatory authorities allow CMS to focus more closely on those materials that have the potential to have the greatest impact on beneficiary enrollment decision-making, without the need for a more burdensome process of collecting and reviewing all communication materials that have little impact on beneficiary choice.

In addition, in the proposed rule under §§ 422.2262(c) and 423.2262(c), we said that "CMS does not generally require *submission and approval* of communications materials prior to use…", which unintentionally did not accurately depict the current processes for material collection through the HPMS Marketing Module. In general, there are two ways that designated materials are submitted to CMS through the HPMS Marketing Module. The "path" a material takes is predetermined by CMS. One submission path includes when plans submit materials to HPMS,

but these materials are not reviewed prospectively by CMS, but are subject to a retrospective review. An example of a material that would fall under this pathway is the EOC. A second submission pathway includes when plans submit materials to HPMS that CMS must review and approve prospectively and prior to their distribution. To clarify these requirements regarding the submission of materials, in this final rule we are editing §§ 422.2262(c) and 423.2262(c) to say that CMS does not generally require *submission, or submission and approval*, of communications materials prior to use.

With regard to the comment that CMS grant a special enrollment period based on receipt of inaccurate or misleading information, CMS has the ability to grant SEPs under §§ 422.62(b)(3)(ii) and 423.38(c)(8)(iii) when a plan or its agent, representative, or plan provider materially misrepresented the plan's provisions in communications as outlined in Subpart V of this part. Such actions are made on a case-by-case basis.

Comment: A commenter offered support of the codification of "intent" and "content" standards currently in the Medicare Communications and Marketing Guidelines. Specifically, the commenter supported CMS' proposal to provide a list of what must be included for a communication material or activity to be considered marketing, believing it eases the interpretation of the previous definition under §§ 422.2260 and 423.2260.

Response: We thank the commenter for their support.

Comment: A commenter voiced concern regarding the use of the word "address" as part of the definition of marketing under §§ 422.2260(2) and 423.2260(2). The commenter stated that the term was too expansive and vague and overly broadens the definition of marketing.

Response: CMS believes that since we changed the definition of marketing in the final rule "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" published in the Federal Register on April 16, 2018 (the April 2018 final rule), we have gained valuable experience through two "marketing cycles"

applying and using the new definition. During this time, we have observed plans using marketing tactics that skirted the definition of marketing by addressing marketing content, such as benefits, premiums, or plan comparisons, without explicitly including the content that are specified in the definition of "marketing" that we proposed and are finalizing in §§ 422.2260 and 423.2260. For example, a plan advertisement that says "Plan X monthly premiums are lower than your current Medicare Advantage plan" would be marketing under our new definition but is not clearly within the scope of marketing materials in the current regulatory definition and guidance. While the advertisement doesn't list the premium or a specific ranking standard, it addresses both of these concepts and is clearly designed to draw a beneficiary's attention to a plan and to influence the beneficiary's enrollment decision. By using the term "address" in the definition we have proposed and are finalizing, we ensure our review of materials such as this example would be marketing under the revised definition adopted in this final rule. The revised definition that we are finalizing provides an important safeguard for Medicare beneficiaries.

Comment: A commenter expressed displeasure with the "benefits disclaimer" not being included in §§ 422.2267 and 423.2267 of the regulation. Prior to August 6, 2019, the MCMG required plans to include on marketing materials that list ten or more benefits the following disclaimer: "this is not a complete description of benefits. Call [insert customer service phone number/TTY] for more information.".

Response: We proposed to codify our current policy as the decision to no longer require this specific benefits disclaimer predates this rulemaking. As plans must provide a Summary of Benefits (SB) and the Pre-Enrollment Checklist (PECL) with an enrollment form, we believe the benefits disclaimer is no longer necessary. The SB outlines key benefits, and also provides information on how to access the Evidence of Coverage (EOC) for a comprehensive list of all benefits. The PECL prompts the beneficiary to review important information before making an enrollment decision, including reviewing the EOC. We believe these documents adequately put beneficiaries on notice that the EOC is the complete list of benefits and that the other documents

are merely summaries. Therefore, we did not propose and are not finalizing a requirement to use the benefits disclaimer used in the past.

Comment: One commenter noted an error in § 422.2266(b). The commenter pointed out that the sentence should be fixed to say ". . . including but not limited to," rather than ". . . including, are not limited to . . ."

Response: We agree with the commenter and are correcting the sentence by replacing "including, are not limited to" with "including" in § 422.2266(b). However, we are not inserting the remainder of the text suggested by the commenter ("but not limited to"), as it is an accepted practice to interpret "including" as meaning "including but not limited to." For consistency, we will apply these changes to § 423.2266(b).

Comment: A commenter expressed concern that we did not include the requirement that Plans/Part D Sponsors may only advertise in their defined service area, unless unavoidable.

Response: We note the decision to no longer restrict marketing outside of a plan's designated service area predates this rulemaking. This decision was made because it is self-policing, as CMS believes that MA Plans and Part D sponsors have little incentive to advertise outside of their service area since beneficiaries must live in the service area to be enrolled in the plan. In addition, CMS believes that there is no negative outcome should a beneficiary view marketing for a specific plan that is not available in their service area, with the exception of marketing about Star Ratings; with Star Ratings, a beneficiary might be misled of confused about the rating of specific plan availing in one area that is offered by a company with a higher rated plan in a different service area. We are finalizing, in 42 CFR §§ 422.2263(c)(5) and 423.2263(c)(5), the current prohibition on marketing Star Ratings outside of a service area that is discussed in the MCMG, section 40.6 (applying the prohibition on misleading marketing and communications) unless the marketing is conveying overall the organization's performance. If the Star Ratings are used in marketing that is distributed outside of the specific service area, the plan must do so in a way that is not confusing or misleading. CMS's current policy is to limit

Star Rating marketing to the service area in which the rating is applicable. This policy is to ensure that beneficiaries are not mislead into believing that a Star Rating earned by "Plan A" applies to "Plan B's" service area. However, we recognize that organizations that are expanding into new service areas would not necessarily have received Star Ratings. We believe that an organization entering a new area should be able to demonstrate the quality of their plan when marketing, provided it is not misleading or confusing. Therefore, we are modifying our current policy to permit the marketing of Star Ratings outside of the service area if done in a way to convey overall organization performance without being misleading or confusing. This is consistent with the overall policy of permitting marketing to occur outside of a plan's service area.

Comment: A few commenters requested that we expand the Annual Notice of Change (ANOC) to include notice to enrollees when providers seen by that enrollee during the past year are no longer in the plan's network (focusing on Primary Care Providers and specialists).

Response: The ANOC is a document geared for mass distribution to all enrollees. Adding specific beneficiary information of this type to the ANOC would not be feasible or advisable given the limitations of current technology, the effort such an addition would require, and the possibility of inaccurate data being provided to enrollees given the fluid nature of provider networks and contracting. Moreover, adding this information to the ANOC would duplicate an existing requirement at 42 CFR § 422.111(e) that plans notify their enrollees when a provider the enrollee regularly sees will no longer be in the plan's network.

Comment: A commenter stated that the prohibition on robocalling is implied in §§ 422.2264 and 423.2264. The commenter requested that CMS list robocalling as a prohibited activity.

Response: We appreciate the comment and agree that the prohibition on unsolicited telephone calls includes robocalling. We are finalizing the regulation text at §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv) with the addition of robocalls to the list of

prohibited activities to eliminate any chance of ambiguity when it comes to robocalls being considered an unsolicited telephone call. We note as well that any other type of telephone solicitation would be prohibited even if not specifically listed because the regulation prohibits all unsolicited telephone solicitation, not merely calls from a live person.

Comment: A commenter requested that CMS prohibit MA plans and Part D sponsors from contacting enrollees based on plan business if the enrollee has an external agent of record. The commenter expressed concern that plans could reach out to a member who was enrolled by an agent, and through a process such as upselling, enroll the member into a different plan, which could result in the agent no longer receiving renewal compensation.

Response: We understand the concern, but believe that this concern — regarding changes in enrollment directly solicited by the plan that lead to changes in agent compensation — is a matter that should be addressed in the contract between plans and brokers. We reiterate that cost plans, in addition to MA organizations and Part D sponsors, must comply with the marketing and communications standards that we are finalizing here based on existing § 417.428, which requires cost plans to comply with part 422, subpart V, with the exception of § 422.2276. In applying those provisions, references to MA organizations should be read as references to HMOs and CMPs, that is cost plans in part 417.

Comment: A commenter noted differences in the wording between the February 2020 proposed rule in §§ 422.2264(a)(4) and 423.2264(a)(4) ("MA organizations are responsible for ensuring sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including, but not limited to, do not call requirements,") and section 110.3 of the MCMG (Plan/Part D sponsor Oversight) ("Plans/Part D sponsors must oversee downstream entities to ensure agents/brokers abide by all applicable state and federal laws, regulations, and requirements."). The commenter expressed concern that the wording might result in states requiring that MA plans and Part D sponsors be subject to a multiplicity of state laws that are expressly preempted by federal law.

Response: Existing regulations at §§ 422.504(i) and 423.505(i) regulate the relationship between plans and their first tier, downstream, and related entities and require plans to maintain oversight and monitoring of these entities and that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instruction. Therefore, we believe that there are adequate standards in place to ensure that the beneficiary protections and marketing and communications rules we are adopting here will apply to related entities, contractors and subcontractors that market on a plan's behalf. In addition, section 1851(h)(7)(A) provides that agents and brokers must be licensed and appointed for the states where they sell and we believe the regulation is consistent with that statutory requirement. Based on this, CMS is not including the provision in proposed §§ 422.2264(a)(4) and 423.2264(a)(4) in the final rule.

Comment: A commenter requested CMS expand the requirement at §§ 422.2274(c)(8) and 423.2274(c)(8) to state that plans must oversee first tier, downstream, and related entities to ensure agents and brokers do not charge beneficiaries a marketing fee.

Response: CMS shares the commenter's concern about charging beneficiaries marketing fees. This final rule governs MA organizations, Part D sponsors, and their first tier, downstream, and related entities (including agents and brokers). As required under §§ 422.504(i) and 423.505(i), MA organizations and Part D sponsors are ultimately responsible for their downstream entities. Therefore, CMS could take compliance action against the MA organization or Part D sponsor for the individual's behavior if they are affiliated with, or acting on behalf of the organization, plan, or sponsor. To clarify this point further, we are finalizing §§ 422.2274(c)(8) and 423.2274(c)(8) with revisions to prohibit marketing consulting fees from being charged when a beneficiary is considering enrollment in a plan. The marketing and communications regulations finalized here also apply to cost plans based on § 417.428; although there are no explicit regulatory provisions in Part 417 regarding the downstream entities and subcontractors of cost plans, cost plans must comply with the requirement that the plan ensure that beneficiaries are not charged marketing consulting fees; we therefore expect that cost plans

will instruct and contract with their subcontractors accordingly to ensure that beneficiaries are not charged these fees.

Comment: Several commenters suggested that CMS do more to protect dually eligible beneficiaries from misleading marketing practices. The commenters suggested that CMS require when an agent/broker disenrolls a beneficiary from an integrated product that the agent/broker provide the beneficiary a clear explanation of the product from which the beneficiary is disenrolling, including explaining how the beneficiary's disenrollment from an integrated product to a non-integrated product might impact their health care service delivery. Commenters also suggested that outbound enrollment verification calls by plans and sponsors include similar information. Commenters also suggested that CMS should require actual contact with the beneficiary during these verification calls.

Response: CMS believes the requirements under § 422.2262(a)(1)(xv), (xvi), (xvii), and (xviii) (and the parallel provisions in Part 423 applicable to Part D plans) function to protect dually eligible beneficiaries from misleading marketing practices. Before additional requirements are considered, CMS will continue to monitor how MA plans and Part D sponsors market to dually eligible beneficiaries to determine if additional requirements are needed. CMS believes that the general requirements set forth in Subpart V of this rule establish the framework necessary for the agency to pursue additional oversight activities to apply the standards in this final rule to specific factual circumstances without further rulemaking. We will also explore changes to agent/broker training and testing to address this.

Regarding outbound enrollment verification, as reflected in the requirement in current §§ 422.2272(b) and 423.2272(b) (which are not being amended in this final rule), plans are no longer limited to verifying enrollment by only phone calls. We now permit plans to confirm enrollment by letter through the mail because our experience has demonstrated that it is virtually impossible for plans to guarantee actual beneficiary contact by phone. Moreover, a hardcopy

letter gives the beneficiary a detailed record that can be saved and provided to others, including the State Health Insurance Assistance Program (SHIP), for help and guidance, if needed.

Comment: Several commenters offered support for the requirement at §§ 422.2262(a)(1)(xv)-(xviii) and 423.2262(a)(1)(xiv)-(xvii) prohibiting MA plans marketing non-D-SNPs as if they were designed for dually eligible beneficiaries or claiming that they have a relationship with the state Medicaid agency.

Response: We thank the commenters for their support.

Comment: A commenter voiced concern that the language found in §§ 422.2262(a)(1)(xvi), stating that plans may not market a non-dual eligible special needs plan as if it were a dual eligible special needs plan, was too vague and ambiguous. The commenter noted that the language goes beyond the language found in the current MCMG and that existing objective limitations are already incorporated in the other subparagraphs under § 422.2262(a)(1).

Response: We disagree with the commenter that the language is vague and ambiguous. Through our experience of investigating complaints concerning D-SNP look-alikes, we have found many examples of plans mimicking the look and language used by D-SNPs in a manner that is confusing or misleading to the beneficiary. While we agree that other provisions in this rule, for example § 422.2262(a)(1)(i), generally protect against misleading materials, given the vulnerability of the dually eligible population, we believe that the requirements as written are warranted and are finalizing these prohibitions as proposed.

Comment: A commenter noted that the guidance regarding dual look-alike plans in the MCMG prohibits "targeting marketing efforts exclusively to dual eligible individuals…", whereas, the requirement in the February 2020 proposed rule prohibits "targeting marketing efforts primarily to dual eligible individuals…." The commenter suggested that the final rule use the "exclusively" standard from the MCMG.

Response: We respectfully disagree. In our experience investigating complaints concerning the marketing of D-SNP look-alikes, the current MCMG language of "exclusively"

has allowed look-alike plan materials to include content that is targeted almost exclusively towards dually eligible beneficiaries with the exception of one or a few sentences noting that the plan was open to all Medicare eligible individuals. Based on this experience, combined with the vulnerability of the dually eligible population, we believe it is important to bolster the language to include those materials that are primarily focused at the dually eligible individuals. As such, we will finalize the language under § 422.2262(a)(1)(xvii) as proposed.

Comment: A commenter was concerned that the language proposed in §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) was too vague. The proposal requires the agent/broker to provide an opportunity for the beneficiary to determine if they want to continue to a marketing event directly following an educational event. The commenter stated this was too vague, resulting in the agent/broker determining if the beneficiary has given consent.

Response: We agree with this concern in part and have strengthened the language at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) that requires agents and brokers make the beneficiary aware of a change in meeting type from educational to marketing and to provide the opportunity for beneficiaries to leave prior to the start of the marketing event. With this change from the proposed rule, we do not believe that the regulation text is vague or requires the agent, broker or other plan representative to guess whether a beneficiary wishes to remain for the marketing event. We also note that agents and brokers, as downstream entities of plans, must abide by the requirements in Subpart V of this rule, including §§ 422.2262(a)(1)(iii) and 423.2262(a)(1)(iii), which prohibits them from engaging in activities that could mislead or confuse Medicare beneficiaries.

Comment: A commenter expressed concern that the revisions found in §§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii) of the February 2020 proposed rule will allow agents or brokers to set up marketing appointments directly following educational events. The commenter stated that "it appears that an agent or broker could immediately step out of the room, so to speak, and conduct a sales event." Similarly, another commenter questioned why a

previous sub-regulatory requirement regarding separation of the time and place of marketing and educational events was not included in the February 2020 proposed rule.

Response: The policy decision to allow marketing and educational events to occur in a close physical and time proximity predates this rulemaking, as reflected in CMS's August 6, 2019 Medicare Communications and Marketing Guidelines Update Memorandum (https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly). We made this change because it can be burdensome for beneficiaries to travel to events. If the beneficiary attends an educational event and wants to hear more plan specific information via a sales event, we believe it should be allowed to happen around the same time, rather than requiring the beneficiary to return on a different day or to a different venue. We, however, share the concern regarding the meeting type switching without the beneficiary being aware. As such, we are further strengthening the language proposed at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), to require that a beneficiary be made aware of a change from educational event to marketing event and given the opportunity to leave prior to the event beginning.

In addition, if a beneficiary is attending a personal marketing appointment with a plan representative, the representative would need to have the beneficiary complete a scope of appointment (SOA) form prior to any discussion as required under §§ 422.2274(b)(3) and 423.2274(b)(3). Finally, current beneficiary protections, such as the requirements under §§ 422.2262 and 423.2262 that plans may not engage in activities that could mislead or confuse Medicare beneficiaries or misrepresent the plan (or the entity offering the plan, such as the MA organization, cost plans, or Part D sponsor), remain in place under the regulations we are finalizing here.

Comment: Several commenters noted that in an HPMS memo released on August 6, 2019 titled "Medicare Communications and Marketing Guidelines," CMS deleted the requirement to

include the hours of operations from the MCMG (section 30.4 of the 2019 MCMG) when listing the customer service telephone number from materials.

Response: CMS thanks the commenters for identifying this issue. Our intention in the HPMS memo was to eliminate the listing of the hours of operation for telesales telephone numbers and not to eliminate the need for including the customer service hours of operation when the customer service call center is mentioned. CMS inadvertently removed section 30.4 entirely. We believe enrollees (or prospective enrollees) should know when they can reach their plan. As proposed and finalized, the substance of §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) remains largely the same: when a plan includes its customer service number, the hours of operation for the call center must be prominently included at least once. However, we are finalizing changes from the proposed regulation text (which addressed the first time the customer service number appears) to focus on ensuring that the information is provided in a useful way to beneficiaries by finalizing a requirement that the hours of operation be prominently included at least once. In addition, we note that we are finalizing a similar change in §§ 422.2262(c)(1)(iii) and 423.2262(c)(1)(iii) regarding inclusion of the hours of operation for 1-800-MEDICARE; we proposed that the hours of operation be included each time the 1-800-MEDICARE telephone number or Medicare TTY appears but are finalizing a requirement that the hours of operation be prominently included at least once on the material that includes the 1-800-MEDICARE telephone number or Medicare TTY. These provisions will ensure that beneficiaries have sufficient information to know how and when to reach the customer service call center.

Comment: A commenter requested that CMS consider updating §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) to say that the hours of operation must be listed "at least once" instead of "the first time" as it was in the February 2020 proposed rule. The commenter stated that changing the requirement would provide flexibility regarding where the hours of operation are placed on materials, resulting in a more beneficiary-friendly location.

Response: We agree that allowing flexibility in where the hours of operation for the customer service call center is listed could result in more beneficiary-friendly materials. We are, however, concerned that updating the requirement to say "listed at least once" may allow the hours of operation to be placed in a way that would obscure this information from beneficiary view or make it difficult for beneficiaries to find how to contact the plan call center. To address this concern, we are finalizing §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) with the standard that the plan must prominently include the hours of operation at least once when including its customer service number.

Comment: Two commenters suggested that CMS should not include rewards and incentives (R&I) as a part of the content that is considered marketing in paragraph (2)(iii) of the marketing definition in proposed § 422.2260(2)(iii). The commenters claimed that the inclusion of reward and incentive (R&I) would consider this to be programmatic content and more appropriately treated as Communications, not subject to the same submission and review requirements. In addition, one commenter said that are two kinds of R&I related content that are communicated to beneficiaries. The commenter referred to them as promotional and programmatic. The commenter said that information plans may include in their open enrollment materials regarding R&I is intended to influence a beneficiary's decision-making process when making a MA plan selection and would be promotional, and rightly characterized as marketing and subject to submission and review requirements. The commenter went on to make the distinction that R&I program content that does not discuss or mention benefits, does discuss and mention healthcare services, but it does not promote or communicate cost-sharing, available network providers, or other benefit details should not be considered marketing. The commenters also noted that a blanket classification of R&I materials as marketing materials, subject to regulatory requirements, would create additional administrative burden and could lead to member confusion.

Response: We respectfully disagree with these comments. For marketing purposes, we view such information as analogous to benefits in the beneficiary's view even though R&I are not benefits *per se*. We believe marketing of rewards and incentives or R&I programs could influence a beneficiary's decision making process when making a plan selection. As such, we believe that its inclusion in the content part of the definition of marketing fits with the overall definition of marketing. We note to the commenter that, for an activity or material to be considered marketing, it must meet both *intent* and *content*. To that point, an activity or material that includes or addresses content about R&I, but does not meet the intent standard specified in the definition at § 422.2260 would not be considered marketing under this final rule. Instead, this activity or material would be considered communications and generally not require submission to CMS. For example, a plan sending R&I information to a current member as a means of influencing the member to get a flu shot would not be considered marketing because the information does not meet the intentions provided under paragraph (1) of the definition of "marketing" under §§ 422.2260 and 423.2260. Conversely, a plan marketing to a prospective member with an advertisement stating "Members of Plan X receive a $15 coupon book by simply getting their flu shot" would be considered marketing as the clearly communicated intent is to use the R&I as a means of influencing the beneficiary's decision-making process when making a plan selection. CMS considers information about Rewards & Incentives to be marketing content and therefore, if the intent standard in the new definition is met, is subject to all the review and requirements applied to communications and marketing content.

Comment: A commenter expressed concern that CMS did not include specific reward and incentives (R&I) communication and marketing requirements as was done in section 40.8 of the MCMG. The commenter noted this means plans can market such programs independently, without context of overall plan benefits to allow individuals to do cost-benefit analyses regarding whether such incentives are worth it.

Response: The decision to remove certain marketing requirements directly targeting to R&I programs from CMS marketing and communication oversight predates this rulemaking. In the MCMG prior to August 6, 2019, plans were directed to provide R&I information in conjunction with information about plan benefits and include information about all R&I programs offered by the MA Plan. We determined that these requirements were overly prescriptive. For example, if a beneficiary requested information about a specific reward or incentive, we determined it unnecessary for a plan to include information about all rewards and incentives. The additional requirements previously addressed in the MCMG, specifically that the rewards not be used in exchange for enrollment and be provided to all potential enrollees without discrimination, are duplicative of other requirements found in this final rule. We direct readers to section D. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V) of this final rule for discussion of requirements for R&I programs. We proposed, and are finalizing, inclusion of information about R&I as part of the content measure for the definition of marketing under § 422.2260. This means that the marketing of R&I (and materials that discuss R&I) must comply with all, in some cases more stringent, marketing requirements set forth in Subpart V, except where otherwise noted.

Comment: A commenter expressed concern that CMS removed the language used in the 2019 MCMG that required plans to support any comparisons with other plans "by studies or statistical data." The commenter acknowledged that the February 2020 proposed rule, at §§ 422.2263(b)(5) and 423.2263(b)(5), includes the requirement that such comparisons be not misleading, which was also in the MCMG.

Response: CMS believes the final rule addresses the commenter's concerns. Under §§ 422.2263(b)(5) and 423.2263(b)(5), as proposed and finalized, plans may not make plan comparisons unless the information is accurate, is not misleading, and can be supported by the plan making the comparison. By using the term "accurate", CMS expects that any plan comparison can be substantiated, including by the use of studies or statistical data or other

information. In addition, the paragraph (2)(ii) of the definition of marketing, at §§ 422.2260 and 423.2260, again as proposed and finalized, makes it clear that plan comparisons are content that is considered marketing, and thus resulting in a greater level of oversight.

Comment: A commenter recommended that CMS develop marketing materials for beneficiaries and providers to educate them on the different types of integrated products and benefits of being in an integrated product. The commenter also stated that CMS should consider requiring agents and brokers that use CMS developed materials to educate all dually-eligible individuals on the availability of highly integrated products in their market and to use beneficiary education materials that include a description of the benefits of integrated product offerings.

Response: We appreciate the comment, but do not believe that additional actions are needed at this time. Extensive information about plan options is available to beneficiaries through Medicare.gov, the Medicare & You booklet and Medicare Plan Finder website. To date, CMS, in partnership with states, has developed standardized, state-specific model materials for MMPs that factually describe the benefits received from Medicare and Medicaid in one plan. In addition, SHIPs play a non-biased educational role in providing information to beneficiaries about their Medicare choices as well. We also note that states play a role in educating beneficiaries regarding integrated products, such as Health Care Options (https://www.healthcareoptions.dhcs.ca.gov/need-help-choosing-program) which is a beneficiary-focused website sponsored by the state of California. We will continue to evaluate the need for additional communications. Finally, we note that plans may continue to market how their plan benefits structure and organization are beneficial to enrollees, including providing information about access to integrated Medicare and Medicaid benefits. We do not believe that additional action by CMS is necessary at this time.

Comment: A commenter requested that the requirement under §§ 422.2262(a)(1)(x) and 423.2262(a)(1)(x) to include the plan type at the end of the plan name should not be required

every time the plan name is mentioned. The commenter noted that such a requirement is not reader-friendly to beneficiaries and seemed unnecessary.

Response: We agree with this comment and are finalizing the regulation at §§ 422.2262(a)(1)(x) and 423.2262(a)(1)(x) with additional text to clarify that plans are not required to repeat the plan type when the plan name is used multiple times in a material.

Comment: A commenter requested that CMS add the word "materially" in front of "inaccurate" in §§ 422.2262 and 423.2262 so it would read "MA organizations may not mislead, confuse or provide materially inaccurate information to current or potential enrollees." The commenter noted that doing so would mirror current guidance standards (presumably 30.7 of the MCMG and § 422.2264 of the current regulation).

Response: As explained in the February 2020 proposed rule, our intent with the revisions to §§ 422.2262 and 423.2262 was to redesignate and reorganize requirements in the current regulations and to codify existing guidance. As current §§ 422.2264(d) and 423.2264(d) and section 30.7 of the MCMG use "materially" in setting forth the requirement, we agree that the revisions finalized here for §§ 422.2262 and 423.2262 should preserve that standard. We are finalizing §§ 422.2262 and 423.2262 to prohibit plans from misleading, confusing or providing materially-inaccurate information to current or potential enrollees.

Comment: In addition to the "mail by" dates provided for various required materials and content under §§ 422.2267(e) and 423.2267(e), one commenter suggested that CMS also codify the earliest date health plans may release this information. The commenter suggested that doing so would simplify the process and allow health plans to prepare for the mailing.

Response: We agree with this comment and that setting earliest date that a plan may begin sending materials for a plan year will help minimize potential confusion for beneficiaries. Therefore, we are finalizing §§ 422.2267(e) and 423.2267(e) with additional text to permit plans to send required materials once a fully executed contract is in place but no later than the due dates listed in §§ 422.2267(e) and 423.2267(e) for each material. Use of the date that the

contract is executed for a particular year ensures that enrollees and potential enrollees are not furnished materials for an upcoming plan year before both the plan and CMS have committed to the plan being offered. We note that only required materials that do not meet the definition of marketing may be sent once a fully executed contract is in place. Any material that meets the definition of marketing, unless otherwise noted or instructed by CMS, may not be distributed until October 1 of each year as required under §§ 422.2263(a) and 423.2263(a).

Comment: A commenter pointed out a typo in §§ 422.2267(e) and 423.2267(e) with the words "or perspective."

Response: We appreciate the commenter catching the typographical error. We are finalizing §§ 422.2267(e) and 423.2267(e) with corrections, to read, "…must be provided to current and prospective enrollees…."

Comment: A commenter requested that CMS also exclude envelopes, ID cards, and call scripts from the requirement to provide the Federal Contracting Statement under §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii). The commenter noted that these materials were excluded from requiring the Federal Contracting Statement in Appendix 2 of the MCMG.

Response: We agree with the commenter in part because, as explained in the February 2020 proposed rule, our intent, with a few exceptions, with the revisions to Subpart V was to redesignate and reorganize requirements in the current regulations and to codify existing guidance. We are finalizing §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii) with an additional exclusion for envelopes. We are not finalizing an exclusion of this required statement from ID cards or call scripts related to sales and enrollment. Sections 1851(d) and 1860D-1(c) of the Act require CMS to provide for activities to disclose the potential for termination of MA and Part D plans to promote informed choice by enrollees; requiring plans to include the Federal Contracting Statement is consistent with the statute. First, ID cards are issued after a beneficiary had made an informed choice and are already excluded from the Federal Contracting Statement requirement. Second, while appendix 2 of the MCMG did exclude disclaimers (including the

Federal Contracting Statement) from call scripts, the Federal Contracting Statement is only required to be a part of materials and information furnished to beneficiaries in connection with information promoting informed choice regarding enrollment into a plan. Consistent with this, we are requiring that any call scripts which meet the definition of marketing, such as sales scripts and enrollment scripts, include this statement. Under this final rule, the Federal Contracting Statement must be verbally conveyed along with the other content of the script.

Comment: A commenter requested that the exceptions that apply to §§422.2267(e)(30)(ii) and 423.2267(e)(32)(ii), the Federal Contracting Statement, apply to all disclaimers specified in §§ 422.2267(e) and 423.2267(e).

Response: We respectfully disagree with this comment. Unlike the Federal Contracting Statement that, with few exceptions, is required on all marketing materials, the other disclaimers listed in §§ 422.2267(e) and 423.2267(e), by design, are limited by their application (for example, when inviting beneficiaries to an event), or are triggered based on specific material content (for example, the Star Ratings disclaimer). Therefore, we do not believe that the general exclusions in §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii) are appropriate for the other required disclaimers and notices.

Comment: A commenter asked if CMS intentionally omitted the requirements found in 60.4.1 of the MCMG (Special Guidance for Institutional Special Needs Plans (I-SNPs) Serving Long-Term Care Facility Residents). The commenter noted that the additional flexibility afforded to I-SNPs is important and should either be added to the final rule or incorporated into sub-regulatory guidance.

Response: We appreciate the feedback. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included an intent to incorporate 60.4.1 of the MCMG into the codified requirements. CMS inadvertently excluded the marketing restrictions for I-SNPs from the proposed regulation text; the preamble of the proposed rule, 85 FR 9110-9111,

however, did make clear that we intended to include all of the policies regarding marketing in a health care setting in section 60 of the MCMG in these updated regulations. We agree with the commenter that this guidance is important to plans, beneficiaries, and caregivers. We are finalizing § 422.2266 with an additional paragraph (f) to codify the current policy addressing how I-SNPs may market in the context of a long term care facility. We note that the requirements in § 422.2266(f) apply to I-SNPs that are contracted with long term care (LTC) facilities as well as those I-SNPs that have an ownership stake in the LTC facility. This new regulation text, combined with the other requirements proposed and finalized in § 422.2266, includes the substance of our existing I-SNP guidance for MA plans. We note that 42 CFR Part 423 regulates the marketing of Part D and we are not finalizing similar regulation text for Part D sponsors. Part D only plans should not be marketing I-SNPs because Part D plans do not provide the medical services and thus would not have contracts with I-SNPs; further, while I-SNPs must be MA-PDs (see § 422.2 definition of specialized MA plans for special needs individuals), compliance with the marketing and communications requirements in § 422.2266(f) will necessarily include materials and activities related to the I-SNP's Part D coverage.

In addition, we also finalizing an additional provision at §§ 422.2264(c)(3)(iv) and 423.2264(c)(3)(iv), to provide that plans may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent/broker is considered unsolicited door-to-door marketing and therefore prohibited.

Comment: A commenter expressed strong support of CMS's proposal to prohibit marketing activities and distribution of marketing materials in dialysis facilities.

Response: We thank the commenter for the support. Stemming from section 1851(j)(1)(D)(i) of the Act, CMS has had a longstanding policy and requirements that limit marketing in healthcare settings. We would like to clarify that our rules have always allowed for marketing activities in common areas. We clarify that the prohibition on marketing activities and

the provision of materials in treatment areas, where patients interact with a provider or the clinical team, does not include a prohibition of marketing activities or the provision of marketing materials in common areas. We are including an edit in sections 422.2266(a)(3) and 423.2266(a)(3) to clarify that, to the extent that dialysis facilities actually do have such common areas, that the same limitations would apply to them as to other healthcare settings. It is not our intent to prohibit marketing for every single area in a facility/health care provider's location and this change in policy for dialysis facilities would mirror the policy as it has been applied previously for all other provider locations.

Comment: A commenter urged CMS to not include the prohibition on providers being compensated for marketing or enrollment activities in the final rule. The commenter noted that, the section 70.5.1 of the Medicare Marketing Guidelines (MMG) issued on 7/20/17 (available here online: https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines_Final072017.pdf), only restricted compensation based on enrollment activities. The commenter stated that the language could be read to prohibit plans and providers from sharing the costs of otherwise permissible provider affiliation activities and advertising.

Response: We respectfully disagree with this comment. The steps taken by CMS to restrict compensation to providers for marketing activities are rooted in ensuring the provider is a neutral party who is offering guidance to patients based solely on what is best for the patient. We note that the decision to preclude plans from compensating providers for marketing activities predates this rulemaking and has been in section 60.2 of the MCMG since it was first released on July 20, 2018. Additionally, the MMG issued in July 2017, under section 70.5.1, still precluded providers from mailing marketing materials on behalf of Plans/Part D sponsors. Under our current policies, affiliation announcements (a provider announcing that they are now [or continue to be in] a plan's network) are communications if limited to that information, and thus would be allowed. However, if a plan is using such an announcement as a veiled means of provider-based

marketing, it would be precluded by this rule, as it would under the MCMG since the July 2018 version. For example, an affiliation announcement that says Dr. Smith is now accepting Medicare Advantage X, then goes on to say that Medicare Advantage X offers $0 copays, and $0 monthly premiums, and that Dr. Smith thinks Medicare Advantage X is the greatest Medicare Advantage Plan would be prohibited by this rule, as well as the current rule, as interpreted in the MCMG.

Comment: Several commenters urged CMS to add specific provisions in the marketing and communications regulations regarding MA special supplemental benefits for the chronically ill (SSBCI) and how plans may market them.

Response: In general, CMS respectfully disagrees that additional regulatory requirements specific to communications and marketing related to SSBCI are necessary. The requirements in Subpart V establish standards and requirements to address a wide range of issues and contexts, rather than having standards for individual benefits, items, issues, and services. This allows CMS to be more dynamic with regard to the ever changing communications and marketing environment. The regulations that we proposed and finalized are as applicable to SSBCI as they are to other benefits covered and offered by an MA plan. However, we recognize that beneficiaries should be aware that SSBCI are not available to all plan enrollees and that the eligibility for these benefits is limited by section 1852(a)(3)(D) of the Act and § 422.102(f); ensuring a clear statement of these limitations guards against beneficiary confusion or misunderstanding the scope of these new benefits. To that end, a new requirement for a disclaimer to be used when SSBCIs are mentioned is being finalized at § 422.2267(e)(32).

Comment: A few commenters expressed concern that marketing SSBCI would lead to inappropriate steering or targeting of beneficiaries. Similar to other comments, the commenters urged CMS to implement specific requirements under Subpart V of the regulation to guard against such predatory sales tactics. A commenter feared that brokers may ask individuals about

their health status and use that information to steer them toward specific plans in violation of anti-discrimination rules.

Response: CMS respectfully disagrees that additional requirements for communications and marketing related to SSBCI should be placed under Subpart V. The requirements, as written in this rule, allow CMS to pursue any marketing or sales tactics that are misleading or confusing to the beneficiary, regardless of whether the violation is tied to specific benefits (like SSBCI). In addition, although CMS understands the concern expressed about agents and brokers asking individuals about their health status, when done appropriately, such activities can be an important part to identifying the best plan for a beneficiary and addressing eligibility for SNPs that serve individuals with severe or disabling chronic conditions. CMS has requirements in place in this rule to ensure plans (including agents and brokers, as downstream entities of plans) act appropriately when it comes to health status, namely §§ 422.2262(a)(1)(vi) and 422.2264(c)(2)(iii)(B).

Comment: Several commenters requested that CMS provide more examples pertaining to the restrictions of marketing during the OEP in §§ 422.2263(b)(7) and 423.2263(b)(7).

Response: We agree that providing more examples and illustrations of how the regulatory standards apply in specific factual situations can be helpful. However, we believe that sub-regulatory guidance is the best location for providing additional examples.

Comment: Another commenter also expressed the need for examples. However, the commenter also cited the need for CMS to more closely monitor marketing activities during the OEP. The commenter noted that if the consequences of marketing during the OEP are not explicit or consistent, it defeats the purpose of prohibiting plans to market during this time.

Response: We agree with the commenter that appropriate oversight is necessary for effective regulatory guidance. The Medicare Advantage OEP was added to section 1851(e)(2)(G) of the Act by the 21st Century Cures Act with a prohibition on unsolicited marketing or marketing materials being sent to Medicare beneficiaries during the OEP and, in the April 2018

final rule, we adopted the specific prohibition in current §§ 422.2268(b)(10) and 423.2268(b)(10) that is being redesignated with additional provisions at §§ 422.2263(b)(7) and 423.2263(b)(7) in this final rule. Since the April 2018 final rule, CMS has fielded several questions from plans concerning what can and cannot be done during the OEP. In addition, CMS has also investigated complaints received concerning plans the complainant felt were not in compliance with the prohibitions of marketing during the OEP. CMS has used this experience to shape the requirements in this final rule, which includes specific provisions regarding prohibited conduct (such as sending unsolicited materials that advertise the availability of this enrollment period and calling former enrollees to solicit reenrollments) and permitted conduct (such as responding to beneficiary requests for sales meetings) in addition to the general prohibition on knowingly targeting or sending unsolicited materials during the OEP. CMS will continue to monitor compliance with the prohibition of knowingly marketing to beneficiaries during the opportunity afforded by the OEP, and take appropriate compliance or enforcement action when necessary. CMS encourages beneficiaries to report any abusive, confusing or misleading marketing practices by plans, agents and brokers by contacting contact 1-800-Medicare. In addition, we encourage reports of potential violations of this requirement.

Comment: A commenter requested that CMS consider lifting the restriction on marketing to beneficiaries during the OEP. The commenter believed information about the OEP should be shared proactively with beneficiaries so that they are aware of the option to switch MA plans if the enrollee's MA plan is not a good fit. The commenter noted that beneficiaries may be losing out on an enrollment opportunity and forced to stay with their existing plan until the next AEP to make a change because CMS prohibits plans from proactively marketing information about the OEP.

Response: The prohibition of marketing during the OEP is statutorily required so we do not have authority to eliminate it. Further, CMS believes that the intent of Congress was to allow beneficiaries to make an enrollment decision during the OEP, without creating a second

opportunity for plans to proactively persuade or attempt to persuade beneficiaries to switch MA plans. Neither the statute nor regulation restricts a plan from providing educational materials or marketing materials if and when the beneficiary proactively reaches out looking for help during or regarding the OEP.

Comment: A commenter agreed with CMS that marketing and advertisements should be restricted during the MA OEP. The commenter noted that during the MA OEP, excessive marketing can be confusing to seniors and leads people to unnecessarily believe that they need to make a plan change. The commenter additionally stated that the OEP should be a time to help seniors process necessary changes that are based on real issues; not those who have been influenced by excessive marketing.

Response: We agree with the commenter and believe the requirements proposed and finalized at §§ 422.2263(b)(7) and 423.2263(b)(7) implement the statutory prohibition and provide the appropriate beneficiary protections.

Comment: A commenter requested that CMS include language in §§ 422.2263(b)(7) and 423.2263(b)(7)(i) to allow general information on websites, as currently permitted in section 40.7 of the MCMG.

Response: We agree with this comment. We are finalizing the §§ 422.2263(b)(7)(i) and 423.2263(b)(7)(i) with an additional paragraph (E) that permits plans to include educational information, excluding marketing, on the plan's website about the existence of the OEP.

Comment: A commenter stated that the language at §§ 422.2263(b)(7)(ii)(C) and 423.2263(b)(7)(ii)(C) stating plans "must not engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales..." was vague and overbroad, as it suggests the intent of the activity alone may determine whether it is compliant.

Response: We respectfully disagree with the comment. Our goal, as when the prohibition on marketing during the OEP was originally codified in the April 2018 final rule, is to implement the statute in a manner that protects beneficiaries without creating undue burden on plans. To

accomplish this, we consider the intent of marketing materials or activities. If CMS focused only on the content of materials or activities, bad actors would be able to evade oversight by simply excluding certain words, while using materials or conducting activities with the same overall focus and intended outcome. We also believe that plans are well equipped to determine if materials or activities are intended to be used or are being used to target beneficiaries during the OEP.

Comment: A commenter requested that CMS revise the regulatory text pertaining to non-renewal notices at § 422.2267(e)(10) to address the earliest date that health plans may release this information. The commenter noted that section 100.4 of the MCMG states information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS.

Response: CMS agrees with this comment. Section 100.4 of the MCMG provides that information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance. As such, we are finalizing §§ 422.2267(e)(10)(i) and 423.2267(e)(13)(i) with additional text to permit release of non-renewal notices after CMS provides notification to the plan. We note that §§ 422.506(a)(2)(ii) and 423.507(a)(2)(ii) state the beneficiary must receive notice by mail at least 90 calendar days before the date on which the nonrenewal is effective; we are not changing or limiting that timeframe in this final rule.

Comment: A commenter suggested that CMS reclassify payments to third parties, addressed in §§ 422.2274(e) and 423.2274(e), as "payments other than compensation." The commenter explained that the change would not only account for payments to third parties, but also for payments to agents/brokers that are not considered compensation. The commenter gave

the example that payment to an agent for completion of health risk assessments is a payment other than compensation because the payment is not for the sale or renewal of a policy.

Response: CMS agrees with the commenter that additional clarification is necessary. We are finalizing §§ 422.2274(e) and 423.2274(e) as a provision identifying payments that are not compensation but are administrative payments. We are finalizing the scope of these payments as proposed, meaning payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, assistance with completion of health risk assessments), but without the limitation that the payments be made to a third party. As proposed and finalized, all payments of this type must not exceed the value of those services in the marketplace. This standard is intended to ensure that plans do not use these administrative payments as a means to circumvent the limits on compensation to agents and brokers. Plans must limit these payments to the amounts that would be fairly negotiated on the open market for the administrative services being performed and should be able to demonstrate that the administrative payments were made for actual performance when necessary. We are finalizing paragraph (e)(2) as proposed but without limiting the provision to payments to third parties.

Comment: A commenter voiced the concern that permitting plans to contact beneficiaries in another line of business could lead to an onslaught of unsolicited marketing. The commenter was especially concerned about unsolicited marketing to dually eligible beneficiaries. The commenter urged CMS to limit plan outreach/marketing to once a quarter, a limitation that corresponds with the LIS special enrollment periods.

Response: CMS understands the commenter's concern. However, CMS does not believe that outreach for plan business has harmed beneficiaries. CMS uses the Complaints Tracking Module to log concerns from beneficiaries and others who call 1-800-Meducare. We have not received complaints related to inappropriate outreach to enrollees regarding plan business. In addition, §§ 422.564 and 423.564 provide beneficiaries who feel they are being overly bothered by such calls the option of filing a grievance with the plan under the part C and D grievance

rules. The intent of allowing contact for plan business is to ensure CMS's rules are not a barrier to a beneficiary gaining access to helpful plan information, rather than exposing the enrollee to unsolicited burdensome contact. We do not agree with adopting the remedy suggested by commenters of limiting contact to once per quarter because doing so may unintentionally limit what could be wanted or needed communication for the enrollee. Instead, we are finalizing a requirement that the plan offer an opt-out when contacting a beneficiary for plan business at §§ 422.2264(b)(2) and 423.2264(b)(2). As a result, plans must respect requests from enrollees to cease calls to enrollees about plan business. We encourage plans to develop opt-out procedures and policies that provide the enrollees the ability to limit calls to particular topics or timeframes as well as opting out of all future calls. We believe this remedy, as opposed to an arbitrary cap on calls, provides enrollees with the means to stop calls should they wish.

Comment: A commenter offered support to CMS's bifurcation of provider activities under §§ 422.2266(c)-(d) and 423.2266(c)-(d). The commenter noted that §§ 422.2266(c) and 423.2266(c) allowed providers to provide fact-based guidance to their patients on MA plans.

Response: CMS thanks the commenter for the support.

Comment: A commenter expressed concern that the language used for the review of communications materials under §§ 422.2261(c) and 423.2261(c) implies that the EOC would require filing, as well as CMS review and approval, before it could be used. The commenter stated that it was not feasible for plans to get an EOC completed after annual bid approval, printed for member requests by 10/15 and accessibility-processed for website availability by 10/15, if plans have to wait for CMS to review and approve the EOC. The commenter also noted that currently CMS requires plans to file the EOC, but it gets "NM" status and is available for use immediately after filing in HPMS.

Response: CMS is not changing the process for the submission and review of the EOC. The EOC is a standardized material, meaning plans must use the language provided by CMS with no modification. As such, the potential for a beneficiary to be misled by an EOC is low, and

therefore, the EOC is not prospectively reviewed. Plans are required to submit the EOC to CMS for retrospective review, and plans must provide CMS with ready access to the EOC should CMS receive a beneficiary complaint about the EOC.

Comment: A commenter requested that the CMS final rule include the qualification under section 30.7 of the MCMG that unsubstantiated absolute and/or qualified superlatives may be used in logos and taglines.

Response: CMS agrees with this comment. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included an intent to incorporate 30.7 of the MCMG into the codified requirements. This exception to the unsubstantiated statement requirement was unintentionally not included in the proposed rule. We are finalizing additional text at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to allow unsubstantiated statements, which could be in the form of superlatives or pejoratives, in logos or taglines. We note that plans are permitted to use unsubstantiated statements only in taglines and logos, which means that plans may not include unsubstantiated statements in larger or longer marketing materials. We further note that it may be possible for some superlatives or pejoratives to qualify as substantiated statements.

Comment: A commenter, citing proposed §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), requested that CMS provide specific guidance in one place on the requirements in the notice for electronic delivery of materials and requested clarification whether plans would be permitted to create their own notice.

Response: Paragraphs (D) and (E) of §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i) outline the content requirements for the notice. In addition, paragraphs (A), (B), (C), and (F) provide additional requirements for a plan to use the flexibility of notice of electronic access to the EOC, Provider and Pharmacy Directories and Formulary without prior authorization from the enrollee.

Provided the requirements under §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i) are followed, plans are permitted to create their own notice.

Comment: A commenter expressed concern that listing the SB as a model material in §§ 422.2267(e)(5) and 423.2267(e)(4) of the February 2020 proposed rule was going to result in the required use of a model. The commenter expressed concern that doing so would impact a plan's freedom to design the SB and explain benefits as they currently can under Appendix 5 of the MCMG.

Response: As proposed and finalized, the requirements for the SB are consistent with the current policy in the MCMG, including Appendix 5 of the MCMG. We clarify here that the term standardized materials, which are specified in §§ 422.2267(b) and 423.2267(b) must be used in the form and manner provided by CMS. Model materials, which are specified in §§ 422.2267(c) and 423.2267(c) are created by CMS is an example of how to convey beneficiary information. As with current policy and practice, plans may customize the SB so long as all required content is included and are not required to use the CMS model SB without customization.

Comment: A commenter noted that the MCMG requires the PECL to be included with the SB, whereas §§ 422.2267(e)(4) and 423.2267(e)(3) of the February 2020 proposed rule would require the PECL be included with the SB and the enrollment form. The commenter explained that while typically the SB and an enrollment form are provided together in a pre-enrollment packet, if a prospective enrollee elects to access plan marketing materials on the plan's website, the individual will access the SB and enrollment form separately. The commenter recommended that CMS allow the checklist to continue to only be included with the SB as required in current guidance.

Response: We agree with this comment in part. We agree that it is unnecessary to require the PECL be included with the SB and the enrollment form. However, the PECL was originally developed as a tool to help beneficiaries consider important questions about their needs and coverage choices and we have always intended it to be reviewed prior to making an enrollment

decision. As such, we believe it best to require the PECL with the enrollment form as opposed to the SB. Plans may include the PECL with other materials, if they choose. We are finalizing §§ 422.2267(e)(4) and 423.2267(e)(3) to require that the PECL be provided with the enrollment form. As finalized, these regulations do not require the PECL to be included with the SB but we encourage plans to do so when it is appropriate and helpful to potential enrollees.

Comment: A commenter pointed out an error to the requirement for mailing statements at § 423.2267(e)(36)(i).

Response: CMS appreciates the commenter bringing this error to its attention. CMS is finalizing § 423.2267(e)(35)(i) (proposed § 423.2267(e)(36)(i)) with a correction to include the same language as proposed and finalized at § 422.2267(e)(34)(i). These regulations require MA plans, cost plans and Part D plans to include the following statement when mailing information about the enrollee's current plan: “Important [Insert Plan Name] information.”

Comment: A commenter requested that CMS clarify that, consistent with current policy, the "Important plan information" mailing statement would only be required for current member mailings, as indicated in Appendix 2 of the MCMG.

Response: CMS confirms that the commenter is correct. Under §§ 422.2267(e)(34)(i) and 423.2267(e)(35)(i), as finalized, plans must include the statement when mailing information about the “enrollee's” current plan, which is synonymous with “current member.”

Comment: A commenter requested that CMS re-evaluate the HPMS timing and submission of the Star Ratings Document to remove the 5-day waiting period. The commenter stated that, because the document is automatically generated from HPMS, there is no value in requiring plans to resubmit the Star Ratings Document back into HPMS as a file and use material, which requires a 5-day waiting period before the document can be used. The commenter requested that CMS apply the same guidance to the Star Ratings document as the Annual Notice of Change (ANOC).

Response: Based on the regulatory definition of marketing under §§ 422.2260 and 423.2260, CMS has determined the Star Ratings Document is a marketing material. Because the collection of marketing materials is required under section 1851(h)(1) of the Act, the Star Ratings Document, as a marketing material, must continue to be submitted via the HPMS Marketing Module under the defined process. CMS is finalizing the requirement that the Star Ratings documents are subject to the 5-day waiting period. This period will provide an opportunity for CMS to ensure that organizations do not alter the document as that document is a key piece required with an enrollment form.

Comment: Two commenters requested that CMS remove the requirement for the Availability of Non-English Translations disclaimer under proposed §§ 422.2267(e)(32) and 423.2267(e)(34). Both commenters referenced the requirement tied to section 1557 of the Affordable Care Act (ACA) as having duplicative requirements. The commenters stated that the Availability of a Non-English Translations disclaimer would result in beneficiaries receiving the disclaimer language multiple times within the same mailing.

Response: CMS understands the concern with duplication. As of this final regulation, the Office for Civil Rights (OCR) finalized the regulations implementing section 1557 of the ACA without requiring disclaimers. Acknowledging OCR's finalized regulations did not include language-based disclaimers, CMS will not finalize the proposed Availability of Non-English Translation disclaimer, proposed §§ 422.2267(e)(32) and 423.2267(e)(34), in this final rule. To clarify, there would be no requirement in this regulation for the Availability of Non-English Translation disclaimer; however, plans must still abide by OCR's current or future requirements on this topic as they have the authority to impose such requirements. As such, CMS believes future rulemaking regarding non-English disclaimers, if appropriate, is best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. In addition, we note that the other paragraphs in §§ 422.2267(e) and 423.2267(e) will be renumbered as compared to the proposed rule as a result.

Comment: Several commenters provided support for CMS including non-English language disclaimers in the proposed regulation.

Response: CMS appreciates the support but has made the decision not to finalize proposed at §§ 422.2267(e)(32) and 423.2267(e)(34) in this final rule and to defer to OCR for possible future rulemaking. CMS has determined that deferring to OCR's oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program.

Comment: Several commenters requested that CMS remind plans about their obligations to comply with section 1557 notice requirements, including "taglines" or disclaimers in the top 15 languages and to conduct enforcement and oversight when appropriate.

Response: We appreciate the comments. We believe it is important for plans to be cognizant of obligations as they relate to applicable rules and regulations that require interpreter services, translation of materials, and associated notices or disclaimers and have included the requirement in this final rule under §§ 422.2267(a)(3) and 423.2267(a)(3).

Comment: Two commenters urged CMS to take this opportunity to revisit §§ 422.2267(a)(2) and 423.2267(a)(2) and require using a threshold of five percent or 1,000 people in the service area, whichever is lower, of a population speaking a language other than English to trigger translations for vital documents.

Response: CMS respectfully disagrees with this comment. CMS previously considered a similar standard when translation requirements were first added to §§ 422.2264 and 423.2264 in the final rule, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes," published in the Federal Register on April 15, 2011. (73 FR 21423, 21512 through 21514) At that time, CMS stated that use of a standard of the lesser of 5 percent or 500 people would result in all PDPs and nearly all MAOs providing translated materials in all languages captured in the ACS data, which would result in a significant increase in the number of plans required to translate and the number

of languages required for translation. Absent definitive evidence to support the sharp increase, this would result in insupportable costs and burden. Although the commenter was suggesting a five percent or 1,000 people in the service area, CMS believes the reasons identified by final rule cited above still apply and that raising the alternative minimum standard to 1,000 people from 500 would not significantly reduce the potential burden. As such, CMS will is finalizing as proposed the provision at §§ 422.2267(a)(2) and 423.2267(a)(c) setting the translation standard at five percent of the individuals in a plan benefit package (PBP) service area.

Comment: A commenter requested that CMS allow the Scope of Appointment (SOA) provision found at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to be satisfied by a simple question on the coverage application, with additional paperwork only required if the appointment topic shifts beyond the scope of Medicare.

Response: Section 1851(j)(2)(A) of the Act requires the Secretary to establish limitations to require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement, which must be in writing if the marketing appointment is in person; section 1860D-4(*l*) imposes the same requirements in the Part D program. The regulations proposed, and finalized, at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), implement these statutory requirements. We believe that using the enrollment form, typically a document that is used at the end of a personal marketing appointment, would not be consistent with the statute. Therefore, we are finalizing these provisions.

Comment: A commenter requested that CMS clarify what is meant by "use of a previous post" as stated in §§ 422.2262(b)(1)(iv) and 423.2262(b)(1)(iv). The commenter stated that it is unclear what types of social media ads would be considered product endorsements or testimonials.

Response: The phrase "previous post" refers to a social media post that had been made in the past or prior to its use, sharing, or posting by a different user. For example, a plan enrollee tweets that they were able to quit smoking thanks to a smoking cessation program offered by

Super Duper Medicare; if Super Duper Medicare shares (by retweeting or otherwise) that tweet with their followers, it would be considered a use of a previous post. Under §§ 422.2262(b)(1)(iv) and 423.2262(b)(1)(iv), as proposed and finalized, this use of the previous post is a product endorsement or testimonial. We will provide additional examples as necessary through sub-regulatory guidance and training.

Comment: A commenter requested that CMS consider changing the training and testing standards at §§ 422.2274(b)(2) and 423.2274(b)(2) to relax the requirements for more seasoned (5 years or longer) agents and brokers. The commenter stated doing so would encourage longevity and stability among private Medicare agents and brokers.

Response: CMS appreciates the comment and will consider this in future rulemaking, but believes further analysis and consideration is necessary before adopting such a policy. This policy would potentially increase the complexity of agent and broker oversight. Further, we believe we should analyze the cost implications, including potential additional costs (or savings) of implementing a tiered approach to agent and broker training and testing.

Comment: A commenter requested CMS clarify that "applicable disclaimers," as used in §§ 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii), are those disclaimers required by CMS.

Response: Sections 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii) refer to notices, statements, disclosures, and disclaimers required for plan use under other statutes or regulations, such as (but not necessarily limited to) the disclaimers required under §§ 422.2267(e) and 423.2267(e). To clarify this point, we have updated the language at 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii) to include notices, statements, disclosures in addition to disclaimers.

Comment: A commenter requested that CMS limit the requirement at § 422.2265(a)(1)(iv) regarding the need to update websites with the most current information within 30 days to only updates to the website that are material changes.

Response: CMS agrees with this comment as it would be overly burdensome to require plans to update non-material changes, such as a new company mascot, within 30 days. Moreover,

non-materials changes are not impactful to a beneficiary's ability to have access to the information needed to make an educated enrollment decision. CMS is finalizing §§ 422.2265(a)(1)(iv) and 423.2265(a)(1)(iv) with revisions to limit the requirement to update the website to material changes. CMS is finalizing the remaining substance of the regulation as proposed.

Comment: One commenter requested that CMS complete a thorough review of the website requirements to ensure consistency with current guidance as well as inclusion of any requirements outside of the MCMG. The commenter provided two examples. They noted that the Final Rule published on February 12, 2015 (CMS- 4159) required plans to post their disaster and emergency policy annually on the website and the CY 2014 Final Call Letter required plans to have a dedicated Medication Therapy Management MTM program linked from their plan website and it be accessible by clicking through a maximum of two links.

Response: We agree with this commenter and confirm the two requirements noted. We are finalizing § 422.2265(b) with a modification to include a requirement to post disaster and emergency policy annually as outlined under § 422.100(m)(5)(iii). We are finalizing § 423.2265(b) with a modification to include the most recent MTM program website requirements. While CMS strives to list all website requirements under §§ 422.2265 and 423.2265, we note that the lack of a requirement in these sections does not remove plan responsibility for compliance if requirements are adopted elsewhere.

Comment: A commenter recommended CMS align Provider Directory PDF web posting requirements with MCMG section 70.2 (Searchable Formularies and Directories), which indicates that a searchable tool (for example, search engine/database) may be a substitute for downloadable PDF directories as long as all instructions and template information are provided.

Response: CMS respectfully disagrees with this comment. Currently, the regulation at § 422.111(h)(2)(ii) requires the MA plan's website to have information (names, addresses, phone numbers, and specialty) about network providers. Our current guidance, in MCMG section 70.2,

provides that organizations that have a searchable directory on their website are not required to have a downloadable directory on their website. However, regulations at §§ 422.111(h)(2)(ii) and 423.128(d)(3) still require organizations to provide materials in hard copy when requested. Therefore, the provision of hard copies of provider and pharmacy directories is currently a requirement for plans. In addition, now that a greater number of materials may be made available electronically under §§ 422.2267(d)(2) and 423.2267(d)(2), we believe that it is even more important for beneficiaries to have access to a PDF of the compete directory or formulary; this is especially true for the provider directories because prior consent from the enrollee is not required for a plan to use electronic delivery instead of mailing hard copies for provider directories. Our electronic delivery regulations permit organizations to notify individuals that certain materials can be accessed via a website or other method. These materials, unless requested by the beneficiary, will not be mailed in hard copy. As proposed and finalized, §§ 422.2265(b)(3) and 423.2265(b)(3) require plans to post a pdf or copy of a printable version of their provider and pharmacy directories on their website. Even though there is great value in making available on the website a tool or functionality that allows the beneficiary to search for a specific provider or drug based on set criteria, searchable formularies or directories do not allow a beneficiary the ability to view or download the directory or formulary as they would if it had been mailed. For that reason, we believe searchable directories and downloadable PDF documents are distinctly different and are not equivalent in their utility to a beneficiary.

Comment: A commenter inquired about the elimination of the requirement that plans use CMS standard icons when marketing a plan's Star Rating. The commenter noted that, previously, plans were not permitted to create their own gold star icon or any other icon of distinction, however, under the revision of the MCMG, plans could create their own gold star icon (or any other icon of distinction) so long as the icon is not misleading or confusing to beneficiaries. The commenter then stated that it was unclear to them how CMS would determine whether a plan-created icon was misleading or confusing.

Response: As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included the ability for plans to create their own star icon, which we proposed at §§ 422.2263(c)(6)(ii) and 423.2263(c)(6)(ii) and are finalizing here. The revision to the MCMG, section 40.6.1, to permit such plans to create their own Star Ratings icons was announced in an HPMS memo updating the MCMG on August 6, 2019 and predates this rulemaking. If warranted, CMS may examine the effects of allowing plans to use their own icons to denote CMS 5 Star Ratings. CMS will take appropriate action against any plan that uses icons that are misleading or confusing to beneficiaries and we intend to use information such as, but not limited to, beneficiary complaints, CMS marketing reviews, and CMS surveillance activities to identify violations of the prohibitions on misleading or confusing beneficiaries. At this time, we believe that providing plans with this flexibility, while also continuing to prohibit misleading marketing and communications, is appropriate. We note that we proposed and are finalizing the longstanding requirement that low performing plans use the specific CMS-created Low Performing Icon, state what that icon means, and may not attempt to refute or minimize their Low Performing Status, as stated in §§ 422.2263(c)(7) and 423.2263(c)(7). In situations where a plan has been assigned the Low Performing Icon, there is a greater incentive for a plan to mischaracterize its Star Ratings; therefore, by requiring use of the CMS-created icon in those situations, we are sufficiently guarding against the negative consequences of allowing plans to create and use their own Star Ratings icons. Additionally, we will continue to rely on the practices we have developed, discussed in prior responses, for determining whether marketing language and methods are misleading or confusing, including the use of plan-created icons.

Comment: A commenter was concerned about the limited enforcement in the marketplace regarding marketing and referral fees. The commenter suggested that instead of making changes to the requirements, CMS should improve its coordination with state departments of insurance to enforce existing regulations.

Response: CMS has mechanisms in place to monitor agent and broker behavior in the marketplace, including prospective and retrospective marketing reviews, CMS regional office account manager oversight, ad hoc review by CMS Central Office staff, notification by peers (that is, other health plans), and notification through 1-800-MEDICARE (via the Complaints Tracking Module (CTM)) on a case-by-case basis. Additionally, CMS reviews agent/broker payment data in the HPMS agent/broker payment database for anomalies. CMS has a memorandum of understanding (MOU) with all states to facilitate coordination with state Departments of Insurance in order to share information and work with these departments as appropriate. CMS also may take compliance or enforcement action if it determines plans are not adhering to CMS' requirements, including the requirements at §§ 422.504(i) and 423.505(i) for the oversight of first tier, downstream, and related entities, which includes for agents and brokers.

Comment: A commenter suggested that individuals not discuss benefits with beneficiaries in any Medicare plan unless they are licensed and certified.

Response: CMS believes beneficiaries need to understand their benefits and to require a beneficiary to only speak to a licensed and certified agent about the benefits in a plan would be burdensome to both the beneficiary as well as the plan. For example, CMS does not require a customer service representative (CSR) to be licensed and certified to answer a beneficiary calling to determine what the co-pay would be for a medical procedure. The requirements in §§ 422.2272 and 423.2272 are designed to ensure that an individual conducting marketing activities (that is selling) and enrolling individuals into a plan are licensed and certified. CMS also has rules in place at §§ 422.503(b)(4)(vi)(F), 422.504(i)(3)(iii), 423.504(b)(4)(vi)(F), and 423.505(i)(3)(iv) requiring that MA organizations and Part D plans contractually require downstream and first tier entities to comply with Medicare rules when doing Medicare business. We believe these requirements appropriately safeguard the beneficiary without the need for additional restrictions.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the comments, we are finalizing the proposed changes to amend part 422, Subpart V (§§ 422.2260 through 422.2274) and part 423, Subpart V (§§ 423.2260 through 423.2274), with some modifications. Some comments alerted us to typographical errors in either the preamble or regulatory text of the proposed rule; we are finalizing the regulation text with those necessary corrections. Some comments requested immediate clarification of our intentions or semantics, which we have provided as appropriate. Some comments were ultimately requests for clarifications or for additional guidance and, in most cases as noted in our responses to those comments, we intend to update our sub-regulatory guidance to clarify those instructions. There were some comments that caused us to rethink the nature of our proposed changes. We have also made technical and grammatical changes to some provisions without changing the substance of the proposed policy. Finally, we are finalizing the following substantive changes compared to the proposed provisions in addition to the substantive changes discussed in our responses to comment (e.g., the revision to §§ 422.2264(c)(3) and 422.2264(c)(3) regarding appointments with residents of long-term care facilities).

We are making four changes that are not specifically based on comments. First is with regard to how required content (disclaimers) outlined under §§ 422.2267(e) and 422.2267(e) are classified as either standardized under §§ 422.2267(b) and 423.2267(b), or as model under §§ 422.2267(c) and 423.2267(c). We have reconsidered some of those classifications to provide for more flexibility for certain disclaimers by changing them from standardized to model content. This change will give plans the option to adjust the language used to convey the required message (that is, the disclaimer) in a manner that is both understandable and consistent with other plan-based communications. Aside from providing more flexibility, the requirement for when the noted content must be used, as well as the beneficiary protections afforded by the substantive message the content is conveying, remains the same.

The following required content is changing from standardized to model:

- §§ 422.2267(e)(31) and 423.2267(e)(33), Star Ratings disclaimer
- §§ 422.2267(e)(33) and 423.2267(e)(34), accommodations disclaimer
- §§ 422.2267(e)(36) and 423.2267(e)(37), provider co-branding disclaimer
- § 422.2267(e)(37), out of network non-contracted provider disclaimer
- § 422.2267(e)(38), NCQA SNP approval statement

We remind plans that, as required under §§ 422.2262 and 423.2262, the language used for required content may not mislead, confuse, or provide materially inaccurate information.

Second change, we are finalizing §§ 422.2261(a)(2) and 423.2261(a)(2), with the heading *Submission, review, and distribution of materials*, with modifications from the proposal. In the February 2020 proposed rule, we proposed that materials must be submitted to the HPMS directly by the MA organization and that third party and downstream entities are not permitted to submit materials directly to CMS. This provision was, in part, based on technological limitations of the HPMS Marketing Module that did not have a means for third parties to submit materials directly to CMS. During the time between publishing the NPRM and this final rule, we have begun updating the HPMS Marketing Module. As a part of this update, we are considering changes that may allow third parties, with the appropriate safeguards, to submit materials on behalf of a plan or plans. As such, we are updating the final rule to include §§ 422.2261(a)(3) and 423.2261(a)(3) which state that unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS. This added flexibility will give the agency the ability to grant third party access in the future.

Third, we are finalizing a change to remove ambiguity from the prohibition on providing gifts unless they are of a nominal value under §§ 422.2263(b)(2) and 423.2263(b)(2) by clearly indicating the provision is applicable to all beneficiaries, that is both current and potential enrollees. In the February 2020 proposed rule, we proposed edits to the language in the existing regulations (§§ 422.2268(b)(2) and 423.2268(b)(2)) to cite the HHS OIG guidance governing nominal gifts for Medicare beneficiaries. In doing so, our intention was for this requirement to

apply to both current and potential enrollees (that is those eligible for Medicare), as is the case with the OIG's requirements as well as our current requirements found under section 40.4 of the MCMG. Sections 1851(j)(2) and 1860D-04(l)(2) of the Act effectively prohibit gifts unless they are nominal gifts to prospective enrollees by requiring that limitation to be included in marketing standards established for the Part C and Part D programs. In addition, section 1856(b) authorizes CMS to adopt standards to implement the statute and section 1857(e)(1) of the Act authorizes the adoption of additional contract terms that the agency determines are necessary and appropriate and not inconsistent with the Medicare statute. Similar authority in connection with the Part D program is in section 1860D-12(b)(3) of the Act. Under this authority, we are finalizing the prohibition on gifts to any beneficiary, except for nominal gifts that are within the value set in the OIG guidance that are offered to all beneficiaries. This is consistent with our current policy. CMS has historically viewed prohibitions on gift giving to apply to both prospective and current plan members and Medicare beneficiaries are prospective enrollees. This prohibition protects beneficiaries from making an adverse enrollment decision because they were influenced by the receipt of a plan gift. It also protects those beneficiaries who may have been persuaded to remain enrolled in a particular plan based on receiving a plan gift. We are also finalizing a change in §§ 422.2268(b)(2) and 423.2268(b)(2) of the regulation to say that nominal gifts must be provided to "similarly situated" beneficiaries as opposed to the current wording of "all beneficiaries". We are making this change to allow plans to provide nominal gifts as a part of attending an event without obligating the plan to provide that gift to all current and prospective members regardless of event attendance.

Fourth, we failed to list the Part D EOB under § 423.2267(e) (CMS required materials and content), even though we did list the Part C EOB under § 422.2267(e)(2). (For additional information on the Part C EOB, please see § 422.111(k) of this final rule.) This was an oversight when we published the proposed rule. It is important to note that the Part D EOB is already required under § 423.128(e) and its inclusion in the list at § 423.2267(e)(2) is to make it easier

for users of the regulation to identify the various materials and content required as a Part D sponsor. We have also renumbered this section accordingly to account for the addition.

CMS is finalizing these provisions as applicable for coverage beginning January 1, 2022, so these regulations will cover marketing and mandatory disclosures made in 2021 for enrollments made for effective dates in 2022. Additionally, this final rule largely reorganizes current regulations and codifies current policies. As such, CMS encourages MA organizations to take this final rule into account immediately.

F. Past Performance (§§ 422.502 and 423.503)

Since the publication of the first Medicare Advantage (MA) and Part D program regulations in 2005, CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Part D sponsor contract if that organization has failed to comply with the requirements of a previous MA or Part D contract. In the April 2011 final rule, we completed rulemaking that placed limits on the period of contract performance CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance (75 FR 19684 through 19686). In the April 2018 final rule, we reduced the review period to 12 months (83 FR 16638 through 16639).

In the proposed rule, CMS sought to add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance by identifying in the regulation text the criteria we will use to make a determination to deny an application based on prior contract performance. This approach will replace the past performance methodology that CMS developed and issued annually through sub-regulatory guidance.

CMS' overall policy with respect to past performance remains the same. We have an obligation to make certain that MA organizations and Part D sponsors can fully manage their current contracts and books of business before further expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-

compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees. Accordingly, we proposed to adopt three factors, each of which, on its own, represents significant non-compliance with an MA or Part D contract, as bases for denying an MA or Part D application: (A) the imposition of civil money penalties or intermediate sanctions, (B) low Star Ratings scores, and (C) the failure to maintain a fiscally sound operation. We proposed that the presence of any one of these factors in an applicant's record (with the exception of intermediate sanctions imposed on dual eligible special needs plans (D-SNPs) under § 422.752(d)) during the past performance review period could subject it to the denial of its MA or Part D application. Once finalized, these three bases would be added to our already codified authority and may be used to deny an application based on CMS' termination of an applicant's previous contract under §§ 422.502(b)(3) and 423.503(b)(3). We note that while in the June 2020 (85 FR 33796) final rule we adopted § 422.116 (a)(1)(ii), which states that CMS will not deny an application on the basis of an evaluation of the applicant's contracted provider network, we also stated in the preamble to the final rule at 85 FR 33866 that CMS would still consider intermediate sanctions or CMPs imposed based on non-compliance with network requirements as bases for the denial of an application based on failure to comply with a current or previous contract. Also, we decline to consider an application from an organization still covered by the 2-year period during which it had agreed, pursuant to §§ 422.508(c) and 423.508(e), not to submit applications for new MA or Part D contracts as part of a mutual termination agreement entered into with CMS pursuant to §§ 422.508(a) and 423.508(a).

For one of these proposed bases for application denial to be considered, we proposed that the relevant non-compliance must be documented by CMS (through the issuance of a letter, report, or other publication) during the 12-month review period established at §§ 422.502(b)(1) and 423.503(b)(1). Thus, CMS may include in our analysis conduct that occurred prior to the

12-month past performance review period but either did not come to light, or was not documented, until sometime during the review period.

In evaluating applications submitted by organizations with no recent MA or Part D contracting history, we proposed to consider the performance of contracts held by the applicant's parent organization or another organization controlled by the same parent and ascribe that performance to the applicant. Specifically, we proposed to identify applying organizations with no recent prior contracting history with CMS (that is, a legal entity brand new to the Medicare program, or one with prior Medicare contract experience that precedes the 12-month review period). We would then determine whether that entity is held by a parent of other MA organizations or Part D sponsors or otherwise shares common control with another contracting organization. In these instances, it is reasonable in the absence of any recent actual contract performance by the applicant due to a lack of recent Part C or Part D participation, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. Should one or more of the sibling organizations meet one of the bases for denial stated in (b)(1)(i), the application from the new legal entity would be denied.

We proposed to codify the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(A) - low Star Ratings, (b)(1)(i)(B) - intermediate sanction or CMP, and (b)(1)(i)(C) - failure to maintain fiscally sound operation under §§ 422.502 and 423.503. The provision governing the consideration of applicant's parent organizations or sibling entities will be stated at §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).

Comment: A commenter noted that the proposed regulatory provision as it applies to Part D is stated in error. The revisions should have been made to § 423.503, not § 423.502.

Response: We have revised the regulation language to be consistent with our discussion in the preamble to the proposed rule, so that the modification is made to § 423.503.

Comment: Several commenters objected to the use of CMPs as a sole basis for denying an application based on past performance. Some commenters noted that CMPs are imposed in a

wide range of dollar amounts and for a wide range of instances of non-compliance. They maintain that often CMPs are not issued based on what could be considered substantial failures to meet MA or Part D program requirements. Also, CMPs are frequently based on performance information resulting from a routine CMS program audit. Commenters stated that, since CMS audits only a portion of all MA or Part D sponsors in a given year, using CMPs as a basis for evaluating past performance is unfair since organizations are not uniformly at risk of earning a CMP and thus being subject to an application denial based on past performance. As a result, some commenters recommended the elimination of CMPs altogether as a basis for denial. Others suggested that CMS count only CMPs above a certain threshold dollar amount.

Response: We appreciate these comments and acknowledge that, while all CMPs are based on significant non-compliance, the wide range of dollar amounts of CMPs imposed each year reflects a variation in the severity of conduct upon which they are based. It is worth considering whether all CMPs warrant treatment as a basis for determining that an applicant's past Medicare contract performance warrants denial of their MA or Part D contract qualification application. Therefore, we will strike CMPs from the regulation as a basis for an application denial based on past performance. We may consider in a future rule whether we should establish thresholds in dollar amounts or types of non-compliance that would warrant denial.

Comment: Several commenters expressed opposition to the use of just one year of low Star Ratings as a basis for denying an application based on poor past performance. Generally, they stated that one year of Star Ratings was not necessarily a true reflection of an organization's performance and that consideration of a three-year period of ratings was a better basis for making a determination of poor past performance. Adopting this approach would be consistent with the standard used to identify contracts with the low performing icon (LPI) on the Medicare Plan Finder (MPF). Commenters also contend that one year's performance might be an outlier for an organization that otherwise has consistently good ratings. This is a particular concern given the uncertainty surrounding the potential impact of the COVID-19 pandemic on quality

measures. Finally, one commenter suggested that we adopt overall scores as opposed to summary scores as the Star Ratings basis for denial for MA-PD organizations since the overall score reflects the full range of operations of those organizations.

Response: The regulations at §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x) already establish our authority to terminate an MA or Part D sponsor contract in the event that it fails for three consecutive years to achieve at least one summary rating score of at least three stars. Also, for 38 months following such a termination, CMS may deny a contract qualification application submitted by the terminated organization or one of its related entities, per §§ 422.502(b)(3) and (4) and 423.503(b)(3) and (4).

After reviewing comments and reconsidering, we are persuaded that 1 year of low ratings may be considered a contract compliance failure, but not a substantial failure on par with the other two denial bases being finalized in this rule (that is, sanctions and financial solvency). By regulation, we have already established that 3 years of low ratings is a substantial failure, justifying termination. In comparison, enrollment sanctions are almost always based on substantial compliance failures. Also, financial solvency issues by definition pose a significant risk to a contracting organization's ability to substantially comply with a contract. Therefore, those two topics continue to warrant adoption as bases for application denial based on poor past contract performance. Accordingly, in the final rule, we are removing low Star Ratings from the list of bases for an application denial. We note, however, that low Star Ratings remain a basis for the denial of an application during the three years following the CMS termination of a contract based on three consecutive years of low ratings, pursuant to §§ 422.52(b)(3) and 423.503(b)(3).

Comment: Several commenters recommended that a determination to deny an application based on past performance should be based on multiple factors, not the presence of any one of the bases (that is, sanction/CMP, low Star Ratings, or financial risk). This approach would be modeled more like our previous approach to making past performance determinations,

where we used a published methodology that described 11 elements we would consider, along with point values assigned to each and established point total thresholds for denying an application. Commenters believe that, by allowing denial based on the presence of any one of our three proposed bases, our approach does not allow for a comprehensive review of the applicant's true performance.

Response: The two bases for an application denial that we adopt through this rule (enrollment sanctions and financial solvency) each by their nature already capture significant and comprehensive information about an applicant's past contract performance. Therefore, it is appropriate for CMS to rely on the presence of either of the bases to support a determination to deny an application.

CMS may impose enrollment sanctions in instances where it has found that an organization has substantially failed to comply with the terms of its Medicare contract. In our experience, such a determination may be based on a systemic failure of the organization that produces non-compliance across a range of requirements or a comprehensive failure to properly administer a critical MA or Part D plan function. Either way, the information that would support an enrollment sanction would in all instances paint a detailed enough portrait of the organization's performance to warrant the application denial.

Financial solvency goes to the heart of any organization's ability to meet all of its obligations as an MA organization or Part D sponsor. For an organization that cannot meet the programs' solvency requirements, no further analysis of its capacity to take on additional Medicare business is necessary, since this type of non-compliance places in jeopardy the organization's ability to even meet its current contractual requirements.

Comment: Several commenters recommended that CMS should afford applicants the opportunity to correct the performance that would form the basis for a determination that they failed to comply with a current contract before CMS makes a final decision to deny the application.

Response: We believe that a "curing opportunity" is inconsistent with the purpose of the past performance review. In effect, through the past performance denial authority, CMS takes a snapshot of an applicant's performance during a specific period of time and uses that information as a kind of credit report to evaluate whether the applicant should reasonably be entrusted with a new or expanded Medicare contract. In that kind of analysis, the only relevant information is the actual history of significant non-compliance that has occurred during the review period. The fact that the non-compliance occurred in the first place speaks to recent gaps in the applicant's ability to manage its current Medicare business. An applicant curing non-compliance during the review period reassures CMS that the organization should continue to administer its current contract, but a more sustained period of compliance is appropriate to demonstrate that its operations are stable enough to warrant eligibility for new Medicare business.

We also note that the past performance provision has its own built-in cure period in the form of the 12-month review period. By operation of the regulation, CMS reviews a new 12-month period during each annual application review cycle. As a result, past non-compliance does not stay on an applicant's record for a sustained period of time, and an applicant that might have been denied based on past performance in one application cycle can find itself eligible for approval in the very next cycle if it has taken effective corrective action.

Comment: Some commenters recommended that the regulation be revised to exclude intermediate sanctions as a basis when the organization has cured the relevant non-compliance and the sanction has been lifted during the review period. The commenters maintain that the lifting of the sanction is evidence that the organization has restored its ability to successfully manage its current operations and therefore should be eligible to apply for additional contracts.

Response: For the purposes of assessing qualification for a new MA or Part D contract, we believe that we should consider all instances of failure to comply described in the regulation that occurred throughout the twelve-month review period. While, of course, CMS expects all sanctioned organizations to move promptly to complete the necessary corrective action to have a

sanction removed, we believe that in any instance, the fact that a sanction had to be imposed at all speaks to the stability of the organization and is relevant to whether it should be approved for a new contract. The applying organization will receive credit for resolving the non-compliance that warranted the sanction during the next past performance review period, when, presumably, the organization will not have an active sanction in place at any time during the applicable 12-month review period.

Comment: A commenter advocated that our past performance authority should not be applied to applications where the purpose is not for the applicant to qualify for a new contract or a current contract with an expanded service area, but for a parent organization to restructure their existing set of MA or Part D sponsor contracts. The commenter noted that parent organizations periodically restructure their Medicare managed care business without taking on new Medicare business. Often this is done through one affiliate of the parent applying to qualify as an MA organization so that it may assume responsibility, through novation, of a contract held by another of the parent's affiliates or through consolidation of two current contracts. The commenter is concerned that our proposed policy would preclude parent organizations from making legitimate reorganizations of their business arrangements. Therefore, the commenter urges us to adopt an exception to our use of poor past performance as a basis for denying MA and Part D applications when they are part of a parent organization's plan to reorganize its contracting arrangements

Response: We note that under the regulation, parent organizations are not precluded from reorganizing their business arrangements. CMS conducts the past performance analysis at the level of the contracting entity. Parent organizations looking to have other entities take over one of their subsidiary's Medicare contracts can select an entity that already has an MA or Part D sponsor contract for that purpose. Assuming that the experienced entity does not meet any of the bases for a past performance-based denial, the entity would be eligible for approval to take over the contract held by its sibling company.

The only instance where CMS considers the past performance of an entity other than the applicant is when the applicant does not currently hold an MA or Part D sponsor contract but is related to a parent organization that has at least one subsidiary that is an MAO or Part D sponsor. In that instance, if one of the parent's subsidiaries met the criteria for a past performance-based application denial, we would deny the application from the "inexperienced" entity. While the application approval would not necessarily result in additional or expanded Medicare business for the parent organization, allowing another contracting entity with no Medicare experience of its own but related to an entity with demonstrated compliance issues does not promote the effective administration of the Medicare program. Even if the parent organization is seeking only to rearrange the contracting entities holding its Medicare contracts, and not to expand its number of contracts, plan offerings, or enrollees, it still would be looking to add to its roster of qualified contracting entities at a time when its efforts should be focused on bringing all of its current contracting entities into compliance with their contracts. In effect, the parent organization would be attempting to expand its Medicare business capability without focusing attention on resolving existing weaknesses in its operations. We do not believe that parent organizations should be permitted to evade our past performance review authority in that manner.

Comment: A commenter stated that organizations that acquire poor performing contracts should not have the performance of the acquired contract counted as part of the parent organization's past performance. The commenter noted that the acquiring organization should have time to focus on improving the performance of the newly acquired contract, for which it had no responsibility, without having to jeopardize its opportunity to pursue other MA or Part D lines of business.

Response: We agree with this comment. The commenter is in effect requesting that we codify the "grace period" policy we had previously included in the Past Performance Methodology. Specifically, when an organization acquired a contract with a record of issues

related to non-compliance, under the Methodology, the purchasing parent was afforded a two-year period, calculated from the date of closing, before any negative performance by the purchased entity or contract would be imputed to the parent's existing entities. We adopted this policy in recognition of the fact that the enrollees in the non-compliant plans, as well as CMS, can benefit from a stronger organization taking over responsibility for a poor performing contract. The acquisition of a Medicare contract by a competent contracting organization is much less disruptive to plan enrollees than termination or non-renewal, which would require enrollees to obtain different Medicare coverage, often resulting in different benefit plans and providers. We believe, in the context of the evaluation of contract qualification applications, that it is important to the administration of the MA and Part D programs that qualified organizations not be discouraged from pursuing acquisitions that could resolve issues created by non-compliant contracting organizations and result in uninterrupted access to benefits and providers for the affected enrollees. To ensure that our past performance policy supports that goal, we are amending the regulation to exempt organizations for two years following the completion of an acquisition from the provision that applies the past performance record of other subsidiaries of a parent to an applicant from the same parent with no Medicare contracts. This provision will remove any concerns an acquiring organization might have that taking on a poor performing contract would compromise its ability to submit a successful contract qualification application.

Comment: A commenter recommends that we provide clarification regarding our use of the term, "may" in the regulation text for this provision. Specifically, the commenter notes that language at § 422.502(b)(1)(i) stating that, "An applicant *may* be considered to have failed to comply with a contract . . ." [emphasis added] conveys the message that CMS may or may not deny an application from an organization that meets at least one of the proposed criteria. The commenter also states that such an interpretation means that applicants meeting the criteria should have the opportunity to present information about extenuating circumstances. The

commenter asks that if CMS intends that there be no flexibility in the application of our denial authority, we should make that explicit in the regulation text.

Response: As we stated in the preamble to the proposed rule, by adopting these new past performance review criteria, we sought to "add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance." Accordingly, we proposed to establish three clear bases for denial, each of which on its own is sufficient to establish conclusively that an applicant has failed in a significant way to comply with MA or Part D requirements. This streamlined approach differed from our previous approach of publishing an annual Past Performance Methodology, through which we would announce the scoring of the multiple performance elements we would consider and how we would score applicants' past performance, including setting point thresholds to identify those whose application would be denied. In establishing all of our review criteria in regulation and streamlining the number of factors to be considered, we intended to convey to applicants that CMS will deny any applicant that meets any of the new bases for a denial based on past performance. Therefore, organizations should expect that we will not consider requests that we exercise flexibility in the application of the new criteria and grant an approval to an application that meets the denial criteria.

With respect to requesting an opportunity to provide information about extenuating circumstances to CMS for consideration, we note that our regulations still provide the opportunity for denied applicants to request a review by a CMS hearing officer, and if unsuccessful there, by the Administrator. More significantly, enrollment sanctions have their own reconsideration process through which an organization may assert that extenuating circumstances justify a CMS decision to decline to impose the sanction.

Comment: A commenter urged that the past performance review should not include contracts that the applicant has already non-renewed or terminated for the upcoming contract year.

Response: We believe that the past performance analysis must be based on an applicant's actual performance history, which should not be subject to revision after the fact. An organization that non-renews a particular contract for an upcoming contract year has already established its performance history through its operation of that contract. The non-renewal does not change the fact that there is record of performance for CMS to review and consider in evaluating whether that entity deserves a new or expanded MA or Part D contract. Moreover, we would be concerned that adopting the commenter's policy would create the wrong set of incentives for contracting organizations. They should be encouraged to improve the performance of their existing contract rather than abandon the contract, and its enrollees, for the opportunity to seek to operate a new set of plans under a new contract.

Comment: A commenter questioned us to clarify that the analysis of past performance under this provision is to be done of the contracting organization and not of all contracts controlled by its parent organization. The commenter believed that our previous application of the past performance authority was done at the parent organization level and unfairly punished large parent organizations that controlled an extensive number of Medicare contracts.

Response: The new provisions we adopt in this rule continue our general policy of evaluating the past performance of the contracting organizations that have submitted applications, not their parent organizations. We have codified here the exception to that policy that we established under the previous Past Performance Methodology. That is, when an organization that does not hold an MA or Part D sponsor contract but is related to a parent organization that does hold at least one contract itself or through another subsidiary, we do apply the past performance record of the experienced subsidiary to the new applicant.

Comment: A commenter expressed support for our decision to exclude enrollment sanctions imposed against D-SNP organizations from consideration as a sanction that would form the basis for a past performance-based application denial.

Response: We appreciate the commenter's expression of support.

Comment: One commenter agreed with our proposal not to penalize an MA organization based on non-compliance with integration standards at the plan level. They suggested that CMS provide an initial enforcement safe harbor from enrollment sanctions for D-SNPs who have made a good faith effort to negotiate SMAC contracts with states. They stated that imposing these sanctions on D-SNPs while implementing look-alike standards could mean that beneficiaries could lack access to transition into otherwise compliant D-SNPs.

Response: We appreciate the support for excluding D-SNP intermediate sanctions for failure to implement the BBA of 2018 D-SNP requirements from past performance. However, changes to the D-SNP intermediate sanction policy are out of scope for this regulation.

Comment: A commenter questioned CMS to clarify whether an enrollment prohibition imposed pursuant to §§ 422.2410(c) and 423.2410(c) against an organization that failed for three consecutive years to meet the minimum medical loss ratio (MLR) threshold would count as an enrollment sanction for the purposes of a past performance-based application denial.

Response: We intended to include all enrollment sanctions, including those based on the failure to meet the minimum MLR, as a basis for application denial based on past performance, with the exception of those related to the failure of D-SNPs to integrate Medicare and Medicaid benefits, which we specifically excluded. The failure to reference the MLR sanctions in the proposed rule was simply a drafting oversight since that sanction authority resides in a different part of the MA and Part D regulations than Subpart O of Parts 422 and 423 where the general enrollment sanction authority resides. Accordingly, we are revising § 422.502(b)(1)(A) to add, "an enrollment sanction imposed pursuant to § 422.2410(c)" and § 423.503(b)(1)(A) to add "an enrollment sanction imposed pursuant to § 423.2410(c)" to the statement of enforcement-related bases for CMS to deny an application based on poor past performance to make explicit the imposition of an MLR sanction as a basis for application denial.

Congress established the significance of the MLR requirement by mandating as part of the MA statute at section 1857(e)(4)(B) of the Act and incorporating by reference into the Part D

statute through1860D-12(b)(3)(D) of the Act that organizations that consistently fail to meet the 85 percent threshold should be prohibited from accepting new enrollments until they can demonstrate that they comply with the MLR requirement. Since the failure to meet the MLR requirement for three consecutive years is subject to the same penalty that may be applied to all other forms of substantial compliance failures, it follows that we include the MLR failure among the bases for an application denial based on poor past performance.

Comment: A commenter maintained that contracts with low enrollment or a large portion of plan enrollees of low socioeconomic status (SES) should not be subject to application denials based on poor past performance.

Response: The commenter provided no explanation of why, specifically, organizations that operate plans with low enrollment or with a large portion of beneficiaries with low SES should be excluded from the past performance review standard. These characteristics should have no bearing at all on two of the new bases for denial, financial solvency and intermediate sanctions.

No matter the level of a Medicare plan sponsor's enrollment or its proportion of beneficiaries with low SES, it must have sufficient financial resources to meet adequately its obligations to provide health care and prescription drug benefits to its members. Also, the required level of financial resources varies at least in part based on an organization's enrollment, so those with low enrollment should not be uniquely adversely affected by the financial solvency bases for application denial.

An MA organization or Part D sponsor must comply with the requirements of the Part C and D programs, regardless of their level of enrollment or proportion of beneficiaries with low SES. Enrollees in low enrollment plans are not entitled to any lesser level of access to Medicare services, nor should CMS expect weaker Medicare contract administration from organizations offering such plans. Therefore, again, organizations with low enrollment are not uniquely in jeopardy of being unfairly subject to an intermediate sanction. Also, as with any sanctioned

organization, a low enrollment organization may always challenge the imposition of the sanction through the appeals process stated in subpart O of Part D 422 and 423. Similarly, enrollees with low SES should receive the same level of Medicare services as all other enrollees, and should receive these services from organizations with sufficient resources to provide them.

Comment: A commenter questioned that CMS continue to produce the Past Performance Outlier report that CMS previously issued every six months to provide contracting organizations information concerning their past performance record.

Response: We will discontinue publishing the Past Performance Outlier report. CMS had adopted the report as a tool to assist organizations in tracking their scores as it was calculated under the multi-factor Past Performance Methodology. Such a report was useful when an organization's performance was assessed various point values and denial was based on those points meeting certain thresholds. However, given the simplicity of the new method for determining whether an applicant will be denied based on past performance, all organizations can track their past performance status for themselves, and no CMS report is needed.

After consideration of these comments, we are finalizing the proposal with the following modifications:

1) We are removing from §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) references to CMPs as a basis for a determination that an applicant has failed to comply with a previous Medicare contract;

2) We are removing the references to Star Ratings as a basis for denial at paragraph (B) of §§ 422.502(b)(1)(i) and 423.503(b)(1)(i) and re-labeling the proposed paragraph (C) concerning fiscal solvency as the new paragraph (B).

3) We are adding language to §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii) to provide parent organizations that acquire poor performing contracts a two-year grace period during which the performance of the acquired contract will not be considered as part of our evaluation of an application submitted by a new subsidiary of the parent;

4) We are adding language to §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) clarifying that enrollment sanctions imposed for failure to comply with MLR requirements for three consecutive years will be considered among the sanctions that qualify for a determination that the applicant failed to comply with a previous Medicare contract; and

5) We are making the technical correction to make the relevant Part D modifications at § 423.503, not § 423.502.

G. Prescription Drug Plan Limits (§ 423.265)

Section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, provides CMS with the authority to establish additional contract terms, not inconsistent with Part D, that CMS finds "necessary and appropriate." Section 1860D–11(d)(2)(B) of the Act provides CMS with the authority to negotiate bids and benefits that is "similar to" the statutory authority given to the Office of Personnel Management (OPM) in negotiating health benefit plans. We interpreted this authority to mean that we can negotiate a plan's administrative costs, aggregate costs, benefit structure and plan management (70 FR 4296). CMS regulations at §§ 423.272(a) and 423.272(b) require Part D sponsors to submit bids and benefit plans for CMS approval. As stated in § 423.272(b), CMS approves the plan only if the plan's offerings comply with all applicable Part D requirements. Similarly, regulations at § 423.265(b)(2) require that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to beneficiary out-of-pocket costs or formulary structures.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plans that PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. CMS has declined to approve more than three stand-alone prescription drug plans offered by a Part D sponsor in a PDP region - one basic plan and (at most) two enhanced plans. A basic plan consists of the following: (1) standard deductible and cost-sharing amounts (or actuarial equivalents), (2) an initial coverage limit based on a set dollar amount of

claims paid on the beneficiary's behalf during the plan year, (3) a coverage gap phase, and (4) a catastrophic coverage phase that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. An enhanced plan is an optional plan offering, which provides additional value to beneficiaries in the form of reduced deductibles, reduced cost sharing, additional coverage of some or all drugs while the beneficiary is in the gap phase of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100, or some combination of those features. Section 423.104(f)(2) prohibits a Part D sponsor (as defined in § 423.4) from offering enhanced alternative coverage in a service area unless the sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

Prior to adopting regulations requiring meaningful differences between each plan sponsor's plan offerings in a PDP Region, our guidance allowed sponsors to offer additional basic plans in the same region as long as they were actuarially equivalent to the basic plan structure described in statute. However, under § 423.265(b)(2), PDP sponsors are no longer permitted to offer two basic plans in a PDP Region because Part D sponsors cannot demonstrate a meaningful difference between two basic plans and still satisfy statutory actuarial equivalence requirements. In addition, we believe that allowing more than one basic plan could result in sponsor behaviors that adversely affect the program, such as the creation of plan options designed solely to engage in risk segmentation whereby one basic plan would target enrollment of the LIS beneficiaries and the second basic plan would target a lower risk population. As it stands, healthier beneficiaries are increasingly being incentivized to enroll in low premium enhanced plans, leading to a higher risk pool in the basic plans. Permitting a sponsor to offer two basic plans in a region could ultimately result in increasing bids and premiums for basic plans, given that LIS auto-enrollment is limited to basic plans. Total government costs would likely increase because CMS pays most of the premium for LIS beneficiaries.

Since the beginning of the Part D program, CMS has consistently tried to ensure that Part D sponsors only market the number and type of PBPs necessary to offer beneficiaries meaningfully different plan options and allow them to carefully examine all of the plan offerings. However, we were persuaded by the argument that allowing sponsors to offer enhanced prescription drug plan offerings that are not meaningfully different with respect to beneficiary out-of-pocket costs could lead to more innovation and provide sponsors with added flexibility to offer health care options that can be tailored to different beneficiary choices with a portfolio of plan options with different benefits, pharmacy networks, and premiums. As such CMS eliminated the meaningful difference requirement between a plan sponsor's enhanced alternative benefit offerings effective for contract year 2019. As a result of eliminating this requirement, we have seen a greater number of enhanced plan offerings.

CMS has examined Part D plan payment data in cases and markets with different numbers of enhanced plans. When looking at this data, we noted that markets with a greater number of enhanced plans have higher costs than basic plans. This was true even when controlling for other factors, such as population health and age. In these cases, the basic component of enhanced plans' bids was found to trend higher than basic plan bids themselves. Given the upward impact to program costs, CMS proposed to codify our policy of limiting the total number of allowed plan offerings by a Part D sponsor in a PDP region to offering no more than three prescription drug plans (one basic and up to two enhanced) per PDP region by adding a new paragraph at § 423.265(b)(2). Since this change would codify our existing practice, this change would not alter any existing processes or procedures within the Part D bid submission and approval process.

We solicited stakeholder input as to the impact of limiting the number of enhanced plan offerings to two. In addition, we sought information on what type of impact expanding the number of enhanced plan alternatives would have and whether there is any need for more than two standalone enhanced plan options per PDP sponsor per PDP region.

We received 15 comments on this proposal, which we have summarized below, and our responses follow:

Comment: Most commenters supported our proposal, citing the benefit of helping ensure that beneficiaries are able to choose from among meaningfully different plan offerings and the harm of risk segmentation. The few commenters that disagreed with the proposal stated their belief that the plan limit unnecessarily hinders sponsors from offering a broader range of more innovative plan designs.

Response: We appreciate commenters support for this proposal as well as the concern that was raised by the commenters that opposed it. Based on our annual review of Part D sponsors plan benefit packages, we believe that the current policy gives plans sufficient ability to innovate. In addition, we believe that the potential negative consequences of permitting sponsors to offer more than one basic plan and two enhanced plans per PDP region, those consequences including risk segmentation leading to additional costs to the government coupled with the risk that there may not be meaningful differences between plans offerings, outweigh any minimal benefit that may occur from allowing Part D sponsors the ability to administer additional plan offerings.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in this response to comments, we are finalizing the proposed changes to § 423.265(b)(2) without modification. However, we recognize that this regulatory provision is closely intertwined with our policy for crosswalking of enrollees, under varying circumstances, within a plan sponsor's benefit offerings. In the event that we decide to reexamine that policy, we may revisit this limitation on the number of PDP plans offered in a region. Although we are finalizing this provision as applicable beginning January 1, 2022, it codifies current policies so we encourage Part D sponsors to take this final rule into account immediately.

H. Definition of a Parent Organization (§§ 422.2 and 423.4)

Pursuant to our authority under sections 1856(b) and 1860D-12(f)(1) of the Act, we proposed to codify our definition of parent organization for purposes of the MA and Part D programs as the legal entity exercising controlling interest in an MA organization or Part D sponsor. We proposed adding a definition for the term "parent organization" to § 422.2 in part 422, subpart A, and § 423.4 in part 423, subpart A, to reflect this understanding.

We proposed the codification to ensure that the MA and Part D programs apply a consistent definition of parent organization. CMS uses the identity of an MA organization's or Part D sponsor's parent organization in a variety of operational contexts, including, but not limited to:

- Determining whether an individual can be deemed to have elected enrollment in a D-SNP based in part on his enrollment in an affiliated Medicaid managed care plan (§ 422.66(c)(2));

- Accounting for contract consolidations in assigning Star Ratings under the Quality Rating System for health and/or drug services of the same plan type under the same parent organization (§§ 422.162 and 423.182);

- Determining whether a new MA contract constitutes a new MA plan for calculation of Star Ratings, benchmarks, quality bonus payments, and beneficiary rebates, (§ 422.252).

- Recognizing an individual's appointment as an MA organization's or Part D sponsor's compliance officer based on his or her status as an employee of the organization, its parent organization, or a corporate affiliate (§§ 422.503(b)(4)(vi)(B)(*1*) and 423.504(b)(4)(vi)(B)(*1*));

- Determining whether an applicant for a new PDP contract is eligible to receive a contract in a particular service area (§ 423.503(a)(3)) after evaluating whether the approval of an application would result in a parent organization, directly or through its subsidiaries, holding more than one PDP contract in a PDP region;

- Determining whether to administer an essential operations test to a Part D contract applicant new to the Part D program (§§ 423.503(c)(4) and 423.505(b)(27), taking into account the exemption from the essential operations test for subsidiaries of parent organizations that have existing Part D business;

- Releasing summary Part D reconciliation payment data at the parent organization level (§ 423.505(o)); and

- Determining whether CMS will recognize the sale or transfer of an organization's PDP line of business, where CMS regulations require the transfer of all PDP contracts held by the selling or transferring sponsor unless the sale or transfer is between wholly owned subsidiaries of the same parent organization (§ 423.551(g)).

We currently define the term "parent organization" for purposes of applying the prohibition against approving an application that would result in a parent organization holding more than one PDP sponsor contract in a region as an entity that exercises a controlling interest in the sponsor. (See § 423.503(a)(3)). In conjunction with the proposal to codify a more detailed definition that would apply throughout the MA and Part D programs, we proposed to delete that language in § 423.503(a)(3).

Under the proposed definition, a parent organization is the legal entity that holds a controlling interest in the MA organization or Part D sponsor, whether it holds that interest directly or through other subsidiaries. The controlling interest can be represented by share ownership, the power to appoint voting board members, or other means. Control of the appointment of board members is particularly relevant with respect to not-for-profit organizations, where there is often no direct corollary to the ownership of corporate shares in for-profit organizations. We recognize that the many ways that one legal entity may have a controlling interest in another legal entity are varied and could take many forms too numerous for us to create an exhaustive list. Therefore, we proposed a definition that includes the ability for us to look at other means of control to be exercised or established.

We further specified that the parent organization cannot itself be a subsidiary of another entity. This ensures that each MA organization or Part D sponsor has a single parent organization for purposes of the MA and Part D programs. For example, if Company A owns 80 percent of Company B, which in turn owns 100 percent of an MA organization, Company A would be the parent organization of the MA organization under the proposed definition.

We explained that the proposed definition codifies current policy and ensures continued consistency throughout the MA and Part D programs. We note that this definition of parent organization will apply in implementing the proposed change to § 422.550 regarding the type of change of ownership that CMS would permit for MA contracts; we discuss that proposal in section V.D. of this final rule.

Comment: A commenter suggested that we further clarify what we mean by "controlling interest" by specifying that it means ownership of a "majority" of shares, appointment of a "majority" of voting board members, and/or by being a sole member.

Response: We do not believe this clarification is necessary or appropriate. We also believe it may unnecessarily narrow the definition of "controlling interest" to one that simply counts shares of stock when organizations may adopt other criteria for allocating board membership and voting rights. For example, two organizations may own equal shares in a legal entity, so that neither holds a majority of shares, but the articles of incorporation or other organizational documents may specify that one of them has the power to cast the deciding vote when they disagree. In such a situation, CMS may determine that the organization with the power to make decisions in case of dispute is the parent despite there not being a single majority shareholder. Conversely, if two organizations owned equal shares of a legal entity and appointed equal numbers of board members and the organizational documents specified that decisions must be made jointly, CMS might determine that neither organization is the parent; additional factual information might be necessary to identify the organization that owns a controlling interest in the particular entity.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the provision as proposed without modification. Although we are finalizing this provision as applicable to coverage beginning January 1, 2022, it codifies current policies so we anticipate that there will be no change in operations or administration of the MA and Part D programs and encourage MA organizations and Part D sponsors to take this final rule into account immediately.

I. Call Center Requirements (§§ 422.111 and 423.128)

In implementing sections 1851(d) and 1860D-4(a)(3) of the Act, CMS established, at §§ 422.111(h) and 423.128(d), that MA organizations and Part D sponsors are required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees, and, for a Part D plan, to pharmacies in the plan network, upon request. One of these enumerated mechanisms includes operating a toll-free customer service call center.

In this final rule, CMS is adding greater specificity and clarity to our requirements for MA and Part D plans by delineating more explicit minimum performance standards for MA and Part D customer service call centers, as well as ensuring greater protections for beneficiaries. We proposed changes to §§ 422.111(h) and 423.128(d) for this purpose and explained in the proposed rule our goals of providing plans clear standards under which to operate their customer service call centers and eliminating uncertainty with regard to CMS's expectations. Customer service call centers include call centers operated for current enrollees, prospective enrollees, and for pharmacies in plans' networks that are seeking information on drug coverage for customers enrolled in a particular plan. For the most part, we proposed, and are finalizing, amendments to §§ 422.111(h) and 423.128(d) to codify existing guidance and CMS's overall policy with respect to operating a toll-free customer service call center remains largely the same. We have always expected MA organizations and Part D sponsors to operate customer service call centers in a way that ensures beneficiaries and pharmacies have timely and accurate access to information about benefits in a manner that they can understand and use. Providing specific performance standards

in regulation text clearly lays out the performance requirements and our expectations for customer service call centers. Additionally, beneficiaries will benefit from CMS holding plans to clearly defined call center standards. As we explained in the proposed rule, failure to comply with the more specific minimum requirements finalized in this rule would represent significant deviation from acceptable call center operational practices and a significant risk to beneficiaries' well-being under our enforcement policies and applicable regulations.

In §§ 422.111(h)(1)(i) and 423.128(d)(1)(i), we proposed that customer service call centers must be open from at least 8:00 a.m. to 8:00 p.m., local time, in all service areas and regions served by the MA or Part D plan, and for Part D plans, that any call center serving network pharmacies or pharmacists employed by those pharmacies must be open any time a pharmacy in the plan service area is open. We reminded stakeholders that MA-PD plans are Part D plans that must comply with Part 423 requirements. We proposed these timeframe standards to lend greater specificity to the current regulation text, which only requires a call center to be open during "normal business hours." We explained that 8:00 a.m. – 8:00 p.m. constitutes normal business hours for beneficiary access, based both on our knowledge of industry-wide practices and our experience with MA and Part D plans' call center operations in particular. Codifying the requirement for call centers serving network pharmacies to be open any time a pharmacy in that network in the plan's service area is open reflects the need to resolve questions about benefits and coverage promptly at the point of sale. The vast majority of current MA and Part D plans meet these standards. We explained that by requiring plans to be open for calls from current and prospective enrollees from 8:00 a.m. to 8:00 p.m. in all service areas or regions served by that Part C or D plan, our proposal would ensure that in instances in which plans operate in service areas that straddle multiple time zones, all beneficiaries and pharmacists have equal access to call center services.

We proposed in §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) a series of minimum requirements that define specific operational requirements for customer service call centers. In

§§ 422.111(h)(1)(ii)(A) and 423.128(d)(1)(ii)(A), we proposed to codify the requirement that the average hold time be 2 minutes or less, with specific text to explain when the two-minute count starts to ensure consistent application of the metric by defining the hold time as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person. In §§ 422.111(h)(1)(ii)(B) and 423.128(d)(1)ii)(B), we proposed to codify the requirements that the call center answer 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction. In §§ 422.111(h)(1)(ii)(C) and 423.128(d)(i)(ii)(C), CMS proposed to codify the requirement that 5 percent or less of incoming call calls be disconnected or unexpectedly dropped by the plan customer call center. These standards both ensure that beneficiaries can consistently access call centers in a timely manner and set thresholds that plans can reasonably attain. We explained that data gathered from our call center monitoring studies indicates that 90 percent of MA organizations and Part D sponsors have average hold times of less than 2 minutes, 87 percent answer 80 percent incoming calls within 30 seconds, and 82 percent have disconnect rates of less than 5 percent. As we further explained, longstanding CMS policy interpreting the current regulatory requirement for the call center to meet standard business practices requires call centers to answer calls within 30 seconds and plans overwhelmingly comply with this requirement.

CMS also proposed to amend §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to further delineate accessibility requirements for non-English speaking and limited English proficient (LEP) individuals. Plans have always been required to provide interpreters when necessary to ensure meaningful access to limited English proficient individuals, as that is consistent with existing civil rights laws. In addition, it ensures meaningful access to Medicare beneficiaries to Medicare-covered benefits. We proposed to further require that interpreters be available within 8 minutes of reaching the customer service representative and that the interpreter be available at no cost to the caller. These requirements are consistent with our interpretation of the requirement

for call centers to meet standard business practices and performance is measured against this standard in our current monitoring and oversight activities. We explained that data from our call center monitoring indicates that 95% of plans already meet this standard.

CMS proposed to add §§ 422.111(h)(1)(iv) and 423.128(d)(1)(v), explicitly requiring that call centers respond to TTY-to-TTY calls, consistent with standards established under existing law governing access for individuals with disabilities at 47 CFR part 604, subpart F. Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act already require the provision of appropriate auxiliary aids and services for individuals with disabilities, such as deaf or hard-of-hearing individuals. We also proposed, at §§ 422.111(h)(1)(v) and 423.128(d)(1)(v), that when using automated-attendant systems, MA and Part D plans must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay systems. See 28 CFR § 35.161, 36.303(d). We explicitly clarified that the requirements proposed at §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) – regarding the average hold time, average answer time, and disconnect rate - also apply to TTY calls. CMS will hold plans accountable for complying with the requirements of §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) when receiving TTY calls. We explained in the proposed rule how the proposed standards are consistent with current CMS interpretation and implementation of the requirement that plans have a call center that meets standard business practices and how. We explained that CMS data shows that 91 percent of plans currently respond to TTY calls within 7 minutes. We solicited comments on adopting the 7-minute response time as a TTY standard.

We proposed to codify our existing interpretations and policies regarding MA and Part D plan call centers as explicit requirements for operating a toll-free customer service call center in §§ 422.111(h) and 423.128(d). We proposed this codification to ensure transparency and stability for plans about the performance standards they must meet.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Several commenters requested that we clarify whether the requirements for customer service call centers apply to call centers operated primarily for sales and marketing to prospective enrollees. The August 6, 2019 HPMS memo issuing the updated Medicare Communication and Marketing Guidelines permitted plans to operate telephone lines designated solely for marketing activities, such as sales and enrollment, under different business hours than customer service call centers for current and prospective enrollees. The guidelines required that sales lines adhere to all other requirements for customer service call centers. Some commenters requested that CMS revise the proposed rule to reflect that guidance permitting sales and enrollment telephone lines to operate during different business hours than customer service call centers for current and prospective enrollees.

Response: Once applicable, the provisions of this final rule will supersede prior, inconsistent call center guidance in the Medicare Communications and Marketing Guidelines. While we proposed to codify existing guidance, we did not include a provision permitting call centers operated for the MA plan to have different business hours based on specific functions. Sections 422.111(h) and 423.128(d) require the call centers to be a mechanism for providing the information described in those regulations to current and prospective enrollees. Using a separate call center for prospective enrollees is not consistent with the current regulation or the proposed revisions. We have therefore reconsidered that prior guidance and will not be using it going forward. Specifically, the policies included in this final rule apply the same requirements applicable to all customer service call centers for current and prospective enrollees, including those used for sales and enrollment. This includes the requirements related to hours of operation.

The guidance issued in in August 2019 to permit separate standards for a sales-only call center has proved difficult for CMS to enforce and confusing for some plans to adhere to. Specifically, plans have expressed confusion about the distinction between sales call centers and

customer service call centers for prospective enrollees. CMS discovered that some plans were inappropriately using their automated answering system to direct calls from numbers not known to be associated with plan enrollees to sales lines, making it difficult for both current enrollees and prospective enrollees to reach the customer service call center they were attempting to call and compromising the ability of current and prospective enrollees to get access to the information specified in §§ 422.111 and 423.128. That information addresses topics and specifics that beneficiaries should have, such as information about benefits (including cost sharing and out of network coverage), access, and enrollment procedures, to make an enrollment election. Returning to a clearer and uniform approach to interpreting and implementing the call center requirements is important to ensure consistency and clarity. We also do not believe that this increases burden on plans, as even after the August 2019 guidance plans were required to continue operating call centers for current and prospective enrollees from 8AM to 8PM. Under this final rule, all plan call centers must comply with the regulation standards.

Comment: Some commenters wrote in approval of what they perceived to be stricter requirements for customer service call centers than CMS previously applied. For example, a commenter noted that the proposed rule would require call centers to connect callers with LEP to an interpreter within 8 minutes 100 percent of the time. A few requested that CMS apply more stringent standards than proposed and currently used, including requiring that all customer service call centers be open 24 hours a day, 7 days a week.

Response: CMS appreciates the support. Our intention in codifying the current policy on customer service call center is to provide a uniform standard for customer service call centers, including call centers for current and prospective enrollees. We were explicit that under our proposal, CMS's overall policy with respect to operating a toll-free customer service call center would remain largely the same and did not describe our proposals as creating more stringent specific standards. We do not believe that the requirements of the final rule represent a significantly more stringent standard than that which we expected under earlier guidance. In

particular, it was not our intention to apply a stricter standard for interpreter availability or call center hours of operation than is described in current guidance. To clarify this, we are finalizing §§ 422.111(h)(1)(iii)(B) and 423.128(d)(1)(iii)(B) with a change from the proposal to reflect the current compliance standard we used evaluating interpreter availability – 80 percent of calls being connected to an interpreter within 8 minutes. We note that plans already largely comply with this requirement of the final rule because 95 percent of plans already meet this standard and, in addition, the 80 percent threshold is consistent with the thresholds codified with respect to the speed of answer.

We are also finalizing, at §§ 422.111(h)(1)(i)(B) and 423.128(d)(1)(i)(A), the proposed standards for operating hours, with a change to clarify that we are not expanding the hours of operation required for customer call centers compared to current practice (except to the extent we are discontinuing the allowance for sales and enrollment call centers to be open for shorter hours than customer service call centers for current and prospective enrollees). Not only do we not believe that customer service call centers for current and prospective enrollees need to be open 24 hours a day, 7 days a week without exception to ensure adequate service to Medicare beneficiaries, we do not believe it is necessary to expand the current policy in section 80 of the Medicare Communications and Marketing Guidelines, which permits call centers to be closed most Federal holidays and on weekends from April 1 through September 30. Therefore, we are finalizing our proposal for hours of operation with the addition of the same exceptions that have been outlined in the Medicare Communication and Marketing Guidelines for several years:

- From October 1 through March 31 of the following year, call centers may be closed on Thanksgiving Day and Christmas Day, so long as the interactive voice response system or similar technology records messages from incoming callers on those holidays and such messages are returned in one (1) business day. This time period encompasses both the MA and Part D Annual Enrollment Period and the MA Open Enrollment period. Plans must not close their call centers for any other days during this period because of the need for both current and prospective

enrollees to reach plans during these generally applicable enrollment periods in order to make informed decisions about their plan choices.

- From April 1 through September 30, call centers may be closed on any Federal Holiday and on any Saturday or Sunday, so long as the interactive voice response system or similar technology records messages from incoming callers and such messages are returned in one (1) business day.

These exceptions have been in place for many years and that there has been no indication that allowing call centers to close on these days has negatively impacted beneficiaries' ability to reach and obtain services and information from plans.

Comment: Some commenters expressed approval of CMS codifying performance standards in the regulation.

Response: CMS appreciates commenters' support for the proposed rule. In this final rule, we are organizing and structuring the addition of these more specific, minimum standards for plan call centers to §§ 422.111(h)(1) and 423.128(d)(1) in a different way than proposed. Instead of replacing the existing regulation text with the more specific standards, we are maintaining the current regulation text that requires plan call centers to be open during usual business hours, provide customer telephone service in accordance with standard business practices, and provide interpreters for non-English speaking and limited English proficient (LEP) individuals. These general performance requirements remain applicable to plan call centers and are not changed by this final rule. Rather, this final rule adds the new specific standards with additional language to clarify how these specific standards will be applicable for coverage beginning on and after January 1, 2022. This means that these standards will apply to call center operations made in 2021 for enrollments made for contract year 2022 (e.g., for call center activities during the Annual Election Period for 2022 that takes place in fall 2021). This clarifies how these specific standards are minimum performance thresholds for plan call centers and illustrates CMS' expectation that plan call centers operate consistent with standard business practices to provide

information and assistance to current and prospective enrollees. Regardless of whether there is a specific, minimum quantitative standard in our regulations, plans should ensure that their call centers provide high quality customer service, at a minimum consistent with usual and standard business practices. The regulations at §§ 422.111(h) and 423.128(d) are clear that call centers are one of several mechanisms by which plans must provide specific information on a timely basis to current and prospective enrollees upon request. By adding certain specific minimum standards, we do not intend to dilute or lower that requirement.

Comment: A few commenters requested that CMS apply the standards for pharmacy call centers to call centers for other health care providers, such as physicians and hospitals. The commenter explained that health care providers also operate 24 hours, 7 days a week and may therefore need real time access to plan representatives to determine coverage for services.

Response: CMS appreciates the suggestion. We understand that hospitals, physicians, and other non-pharmacy providers often operate 24 hours a day, 7 days a week and may wish to have real time access to plan representatives at all times. However, unlike pharmacies, physicians and hospitals do not administer a point of sale benefit. Rather, they bill retrospectively. Therefore, immediate access to the plan through the call center does not appear to be necessary to ensure access to medically necessary covered health care. While CMS is open to considering future rulemaking in this area, we need to gather more evidence and stakeholder input to determine whether it is appropriate or necessary to require plans to operate 24-hour, 7-day-a- week call centers for non-pharmacy providers.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the amendments to §§ 422.111(h) and 423.128(d) regarding call centers as proposed, with five modifications.

Two of the modifications address concerns explicitly raised by commenters. We are finalizing the proposed standards for interpreter availability with the addition that 80 percent of calls requiring an interpreter must be connected to an interpreter within the proposed 8 minutes,

rather than simply requiring all such calls to be connected within 8 minutes. In addition, CMS is finalizing the proposed hours of operation requirements with modifications to provide exceptions for certain federal holidays and on certain weekends so long as callers can leave messages and those messages are returned within one business day. These modifications reflect CMS's intention to largely codify existing policy in this rule.

The third modification that we are finalizing is similar to these two changes. CMS requested comment on whether to adopt the 7-minute TTY response time in the regulation. We received no comments on this issue and have decided to finalize the rule with a requirement that 80 percent of TTY calls be connected to an operator within 7 minutes. As discussed in the February 2020 proposed rule, this reflects current performance by plans (91 percent connect calls within the required time frame) and is consistent with the thresholds codified with respect to speed of answer and interpreter availability.

Fourth, it has come to CMS's attention that 47 CFR, part 64, subpart F applies to state-operated TTY relay systems and not to plan call centers. The proposed rule would have, at 42 CFR 422.111(h)(1)(iv) and 423.128(d)(1)(v)(A), required plan call centers to comply with these standards. However, neither CMS nor plans have authority over state-operated relay systems and Medicare plan call centers do not perform the same function as state relay systems. Therefore, CMS is not finalizing those provisions and is designating the remaining regulation text accordingly.

Finally, we are finalizing the proposed additions to §§ 422.111(h) and 423.128(d) with a slightly different structure to be consistent with how this final rule is adding specific minimum standards and is generally applicable beginning with coverage for 2022.

Although we are finalizing these changes to §§ 422.111(h)(1) and 423.128(d)(1) regarding call centers, with the modifications described above, as applicable with coverage beginning on and after January 1, 2022, it codifies current policies so we encourage MA organizations and Part D sponsors to take this final rule into account immediately.

VI. Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

The intent of this final rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states. The proposals addressed reassessments, service delivery requests, appeals, participant rights, required services, excluded services, interdisciplinary team requirements, medical record documentation, access to data and records, safeguarding communications, and service delivery requirements. The finalized changes would reduce unnecessary burden on PACE organizations, provide more detail about CMS expectations and provide more transparent guidance.

A. Service Determination Request Processes under PACE (§§ 460.104 and 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We issued regulations on grievances at § 460.120, and we issued regulations on appeals at § 460.122. Additionally, CMS created a process under § 460.104(d)(2) to allow participants or their designated representatives to request that the interdisciplinary team (IDT) conduct a reassessment, when the participant or designated representative believes the participant needs to initiate, eliminate or continue a service. The process under § 460.104(d)(2) is commonly referred to by CMS and industry as the service delivery request process. This process serves as an important participant protection, as it allows a participant to advocate for services. As we stated in the Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions final rule (hereinafter referred to as the 2006 PACE final rule), "[t]he provisions for reassessment at the request of a participant [were] intended to serve as the first stage of the appeals process." (71 FR 71292). Section 460.104(d)(2) currently

sets out the responsibilities of a PACE organization in processing each request. Currently, a participant or their designated representative initiates a service delivery request when they request to initiate, eliminate, or continue a service. Once the IDT receives the request, the appropriate members of the IDT, as identified by the IDT, must conduct a reassessment. The IDT member(s) may conduct the reassessment via remote technology when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or their designated representative agrees to the use of remote technology. However, the appropriate member(s) of the IDT must perform an in-person reassessment when the participant or their designated representative declines the use of remote technology, or before a PACE organization can deny a service request. Following the reassessment, the IDT must notify the participant or designated representative of its decision to approve or deny the request as expeditiously as the participant's condition requires, but generally no later than 72 hours from the date of the request for reassessment. If the request is denied, the PACE organization is responsible for explaining the denial to the participant or the participant's designated representative both orally and in writing. The PACE organization is also responsible for informing the participant of his or her right to appeal the decision, including the right to request an expedited appeal, as specified in § 460.122. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised plan of care, the failure constitutes an adverse decision and the participant's request must be automatically processed as an appeal in accordance with § 460.122.

While this section provides an important participant protection, we have heard from stakeholders that the language in § 460.104(d)(2) is overly broad as written, and that even simple requests to initiate a service require a reassessment and a full review of the request by the PACE organization's IDT. Stakeholders have also noted that addressing the service delivery request process in the section of the regulation governing participant assessments undercuts the

importance of the requirements for processing these requests. Additionally, through CMS oversight and monitoring, we have identified a need to better define what constitutes a service delivery request and create clearer guidance on how PACE organizations must identify and process these requests.

We proposed moving the requirements for service delivery requests at § 460.104(d)(2) to a new section of the regulations at § 460.121, titled "Service Delivery Requests." We used the term "service delivery request" because that is the term typically used by industry and CMS to describe these actions, however, we solicited comments on whether we should utilize this term or consider something different. For example, the initial decision to cover a drug in Part D is a coverage determination (§ 423.566), and the initial decision to cover an item or service in Part C is an organization determination (§ 422.566). We requested feedback on whether a term other than "Service Delivery Request," such as "PACE Organization Determination," "Coverage Determination," or "Service Determination," would be preferable.

In addition to proposing that the requirements for processing service delivery requests would be moved from § 460.104(d)(2) into a new section, we also proposed to modify these requirements based on industry feedback and lessons learned through our experience operating the PACE program and monitoring PACE organizations. First, we proposed to reorganize the requirements for clarity and to better align them with the appeals regulations in subpart M of parts 422 and 423, for Medicare Advantage (MA) and Part D respectively, while also ensuring the requirements address the specific features of the PACE program, which is a unique combination of payer and direct care provider. We believe aligning the layout of the regulation and the notification requirements of the initial determination processes in PACE, MA, and Part D would allow us to minimize confusion for participants, who are often familiar with the initial determination and appeals processes in the Parts C and D programs, and would also increase transparency for PACE organizations regarding CMS' expectations.

While the current regulation at § 460.104(d)(2) begins with the requirements for processing a request for reassessment, we added § 460.121(a) to require that a PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of § 460.121. We believe it is important to ensure that PACE organizations develop internal processes and procedures to properly implement this process.

At § 460.121(b), we define what constitutes a service delivery request and what does not. We define what constitutes a service delivery request at § 460.121(b)(1). Currently, the process in § 460.104(d)(2) is triggered if the participant (or his or her designated representative) believes the participant needs to initiate, eliminate, or continue a particular service. At § 460.121(b)(1), we specify that the process for service delivery requests would apply to 3 distinct types of service delivery requests, specifically, a request to (1) initiate, (2) modify, or (3) continue a service.

We note that the term "services" is already defined at 460.6 to include "items," and we proposed, as discussed in section VI.I. of this final rule, to make explicit that this definition is meant to reflect the full scope of the PACE benefit package, and thus also includes "items" and "drugs." Therefore, our use of "service" or "services" throughout § 460.121 always includes any type of PACE-covered services, items, or drugs, and participants have the right to advocate with respect to all types of PACE-covered services, items, or drugs that they believe may be necessary. The language at § 460.121(b)(1) would retain the existing concepts of "initiating" and "continuing" services but would replace the term "eliminate" with the term "modify."

In § 460.121(b)(1)(i) that the first type of service delivery request would be a request to initiate a service. This first type of request is based on the existing language at § 460.104(d)(2). In § 460.121(b)(1)(ii) that the second type of service delivery request would be a request to modify an existing service. We specify that requests to modify an existing service include requests to increase, reduce, eliminate, or otherwise change a particular service. We believe that

defining service delivery requests to include requests to modify an existing service is an important protection, as participants may believe that the services they are currently receiving are not sufficient to meet their needs. For example, a participant may request to increase their home care from 3 hours a week to 6 hours a week because they believe that they are becoming less steady in their gait and they are afraid to be alone for long periods.

The third type of service delivery request at § 460.121(b)(1)(iii), is a request to continue a service that the PACE organization is recommending be discontinued or reduced. This type of request would apply to circumstances where the PACE organization is recommending to discontinue or reduce a service that the participant is already receiving, and the participant wishes to continue receiving that service. An example of this type of request would be a participant that is attending the PACE center 5 days a week and the PACE organization decides to reduce attendance to 4 days a week. If the participant requests to continue attending the center 5 days a week, this request must be processed as a service delivery request under our proposal. Another example would be if a participant is receiving a specific drug, and the IDT makes a decision to stop providing that drug. Under the proposal, the participant's request to continue receiving the drug would be processed as a service delivery request. Through our monitoring of PACE organizations, we have identified instances where a participant requests to continue receiving a service that has been reduced or discontinued, and the PACE organization provides the participant appeal rights under § 460.122 instead of conducting a reassessment as required under the current § 460.104(d)(2). We would include requests to continue coverage of a service in part to ensure that PACE organizations understand that they must process a service delivery request for these situations before processing an appeal under § 460.122. Our revisions to this section, as well as our revisions to the appeals regulation discussed in section VI.B. of this final rule, would establish that the service delivery request process is the first level of the appeals process, and requests to continue a service must first be processed under the service delivery request process prior to an appeal being initiated under § 460.122. We discuss the scope of the

appeals process in greater depth in our discussion of the updates to the appeals process in section VI.B. of this final rule. We also proposed that participants would be allowed to make this type of service delivery request before a service was actually discontinued, to permit the participant to advocate for a continuation of the service. This requirement is reflected in the language we proposed for § 460.121(b)(1)(iii), where we emphasize that this provision relates to a service that the PACE organization is recommending be discontinued or reduced. We believe by wording this requirement in this way, we would make clear that the participant could make a service delivery request as soon as a PACE organization recommends reducing or discontinuing a service. For example, if the IDT was recommending reducing center attendance from three days a week to two days a week, and the participant wanted to continue coming to the center three days a week, the participant could request a service delivery request once the IDT recommended the reduction, even if the reduction in days had not yet been implemented.

We recognize that our proposal defined what constitutes a service delivery request broadly. We also understand that there are circumstances that are unique to PACE where a request may not constitute a service delivery request based on the role of a PACE organization as a direct care provider that is responsible for coordinating and delivering care. Therefore, we proposed an exception to the definition of a service delivery request. In paragraph (b)(2) we specify that certain requests to initiate, modify, or continue a service would not constitute a service delivery request, even if the request would otherwise meet the definition of a service delivery request under (b)(1). Specifically, at § 460.121(b)(2) if a request is made prior to the development of the initial care plan the request would not constitute a service delivery request. This exemption would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased). We believe this approach would be beneficial to the participant and the PACE organization as the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. For example, if the PACE organization is developing the initial plan

of care and actively considering how many home care hours the participant should receive, and the participant makes a request for a particular number of home care hours, that request would not be a service delivery request because the IDT was actively considering that question in developing the plan of care. Once the initial plan of care is developed, if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service delivery request at that time.

While drafting the proposal, we considered other ways to potentially limit the application of the service delivery request process to account for situations where it is possible to adequately address a request without undertaking the full service delivery request process. First, we considered excluding requests for services made during the course of a treatment discussion with a member of the IDT from the service delivery request process, so long as the IDT member is able to immediately approve the service. Ultimately we decided these situations should constitute service delivery requests, in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service delivery requests and those that do not. However, in an effort to reduce burden, we determined that it would be appropriate to process service delivery requests that an IDT member is able to approve in full at the time the request is made in a more streamlined manner than other service delivery requests. We discuss our proposals on this point in more detail in the section relating to § 460.121(e)(2) in this final rule.

We also considered whether we could exclude other types of requests from the service delivery request process. For example, we have received questions from PACE organizations about requests that do not relate to health care or to a participant's medical, physical, emotional, and social needs, such as a participant requesting lemons in their water, or a participant requesting a particular condiment at lunch. We considered proposing to exclude requests that are not related to health care or to the participant's medical, physical, emotional, and social needs, and therefore would not constitute a service delivery request. We strongly believe that any time

a service may be necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, that request should be processed as a service delivery request. We similarly understand that some requests are completely unrelated to the participant's health care or condition. However, we believe that adding a provision to address this relatively insignificant issue would potentially cause confusion for PACE organizations and participants and therefore we did not propose such a provision at this time. We solicited comments on whether specifying that requests unrelated to a participant's medical, physical, emotional, and social needs need not be processed using the service delivery request process would benefit PACE organizations without restricting participants' ability to advocate for any service they believe may be necessary, regardless of whether that is meals, transportation, drugs, home care, or other services provided as part of the PACE benefit, and if so, how we should word such a provision.

We also proposed at § 460.121(c) to specify the individuals who can make a service delivery request. Under the current requirements in § 460.104(d)(2), only the participant or the participant's designated representative may request to initiate, eliminate, or continue a particular service. This proposal would expand the number of individuals who can make a service delivery request on behalf of a PACE participant to include the participant, the participant's designated representative, or the participant's caregivers. We believe that the proposal would be consistent with the current practice of most PACE organizations, in part because caregivers are often also participants' designated representatives; however, it would affirmatively state in regulation that these individuals may make service delivery requests. We believe this would provide an important safeguard for participants, as caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For example, if a PACE participant's wife believes that the participant needs more home care to assist with toileting, bathing and dressing, she would be able to make a service delivery request to the PACE organization and advocate for that service delivery request, regardless of whether she is her

spouse's designated representative. The proposal also aligned with current care plan regulations (§ 460.106(e)) which state that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. Because caregivers are involved in the care planning process and determining what care may be necessary, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant, regardless of whether these service delivery requests result in changes to the plan of care. While a designated representative or caregiver such as a family member may initiate the service delivery request process, the PACE organization remains responsible for issuing a decision based on the individual needs of the participant regardless of the party that initiated the request. We solicited comments on this proposal to expand the number of individuals who can make a service delivery request on behalf of a PACE participant. In addition, we solicited comment regarding whether or not there are other individuals that should be allowed to make service delivery requests on behalf of a participant. For example, in MA and Part D, providers or prescribers can initiate a request for coverage (either coverage determination or organization determination) on behalf of a beneficiary, which allows prescribers or other providers to advocate for drugs or services that are unique to their discipline or scope of practice. In PACE, this would mean that if a participant went to a contracted specialist, that specialist would be allowed to advocate or request a service specific to their discipline. We specifically solicited comments on whether we should specify that prescribers or providers, outside of the IDT, can make a service delivery request on behalf of a participant in PACE.

We also proposed at § 460.121(d) to specify how a service delivery request may be made. The current regulation at § 460.104(d)(2) is silent regarding how a participant or his or her designated representative may request to initiate, eliminate, or continue a particular service. We proposed at § 460.121(d)(1) to permit service delivery requests to be made either orally or in writing. We believe this is consistent with current practice for all PACE organizations. The right to request an initial determination either orally or in writing is provided as an enrollee

safeguard in both MA and Part D (see §§ 422.568(a)(1), 422.570(b), 423.568(a)(1), and 423.570(b)), and given the vulnerability of the PACE population, we believe it is important that PACE participants also have the ability to submit service delivery requests in either form. We also proposed at § 460.121(d)(2) that service delivery requests may be made to any individual who provides direct care to a participant on behalf of the PACE organization, whether as an employee or a contractor. All employees and contractors that provide direct participant care should be trained to recognize and document these requests when they are made by a participant pursuant to § 460.71. Because of the comprehensive nature of the PACE program and the requirement that PACE organizations provide care across all care settings, participants may not know whom they should communicate with when making a service delivery request. For example, certain participants may not attend the PACE center on a routine basis and a home care aide may be the only representative of the PACE organization the participant has contact with frequently. Under this proposal, the participant could make service delivery requests to the home care aide, and those requests would be considered to have been made to the PACE organization. All individuals providing direct care to participants, whether contractors or employees, should be trained to recognize service delivery requests and ensure such requests are documented appropriately and brought to the IDT as part of the training employees and contractors receive under §460.71(a)(1). While we require that all contractors and employees that provide direct care be able to receive service delivery requests from participants, we solicited comment on whether this requirement should be limited to a smaller subset of individuals. For example, we solicited comment on whether we should instead require only those contractors or employees who provide direct participant care in the participant's residence, the PACE center, or while transporting participants to receive service delivery requests.

We would establish new requirements at § 460.121(e) specifying how service delivery requests must be processed. In § 460.121(e)(1) all service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires, but no later than 3 calendar days

after the date the request was made. The existing requirement at § 460.104(d)(2)(iii) specifies that the IDT must generally notify the participant or designated representative of its decision in regard to a request to initiate, eliminate, or continue a particular service no later than 72 hours after the date the IDT receives the request for reassessment. Stakeholders have requested that CMS explain if the current 72-hour timeframe begins when any member of the IDT receives the service delivery request, or when the full IDT receives the request. In order to avoid similar questions about the new service delivery request process we proposed, we also established two distinct timeframes. Specifically, an initial timeframe for the PACE organization to bring a service delivery request to the IDT, and a second timeframe for the IDT to make a decision and provide notice of the decision to the participant. We would include this second timeframe at § 460.121(i), and discuss in more detail later in this section. We believe that creating these distinct timeframes would benefit both PACE organizations and participants. We also believe it is necessary to ensure that once a service delivery request is made, it is brought to the IDT for processing as expeditiously as the participant's condition requires but no later than 3 calendar days from when the request was actually made. In monitoring PACE organizations, we have seen organizations take a week or longer after a request was first made to bring the request to the IDT for consideration. By establishing a requirement that service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires but no later than 3 calendar days from the time the request is made, we believe this would ensure participant requests are handled expeditiously while still ensuring the IDT has sufficient time to process the service delivery request and consider all relevant information when making a decision. We solicited comments on this proposal to establish a new timeframe for PACE organizations to bring service delivery requests to the IDT.

We also proposed at § 460.121(e)(2) to specify an exception to the processing requirements for service delivery requests. Specifically, if a member of the IDT receives a service delivery request and is able to approve the request in full at the time the request is made,

the PACE organization would not be required to follow certain processing requirements. We understand that PACE organizations, as direct care providers, routinely interact with participants when providing care and services. These interactions often include treatment discussions between an IDT member and a participant about what care may or may not be appropriate for the participant to receive. During these discussions, a participant may request a service that the IDT member receiving the request is able to immediately approve as requested based on their knowledge of the participant and the participant's condition. For example, during a physical therapy session, a participant may request a walker to assist in his or her daily activities. If the physical therapist, who is a member of the IDT, determines that the item is necessary and can approve the walker at the time the participant requests it, then the request would not need to be processed as a normal service delivery request. The exception would not apply if the IDT member cannot approve exactly what is requested. For example, if a participant requested 20 hours per week of home care but the IDT member is only willing to approve 15 hours per week, the exception would not apply because the participant's request would be partially denied. Specifically, at § 460.121(e)(2)(i) would require that when a member of the IDT can approve a service delivery request in full at the time the request is made, the PACE organization must fulfill only the requirements in paragraphs (j)(1), (k), and (m). These paragraphs are discussed in more detail later in this section, and generally relate to notice of a decision to approve a service delivery request, effectuation requirements, and record keeping. We also proposed at § 460.121(e)(2)(ii) that PACE organizations would not be required to process these particular service delivery request in accordance with paragraphs (f) through (i), paragraph (j)(2), or paragraph (*l*) of this new section, all of which are discussed in more detail in this section of this final rule.

This exception to how a service delivery request is processed based on feedback from stakeholders that IDT members often have treatment discussions with participants about modifying services and make decisions to accommodate the participants' requests in full at the

time the requests are made. Additionally, we have seen situations where a caregiver requests an item or service that an IDT member is able to immediately approve at the time the request is made. In these situations, it is important that the decision to approve the service is communicated to the participant or the requestor at the time the request is made so that the participant/requestor understands the outcome of their request. If a decision to approve a requested service cannot be made in full at the time of the request, the PACE organization must fully process the service delivery request in accordance with all relevant paragraphs of this new section. If an IDT member can quickly approve a service as being necessary for the participant, we do not believe that it would benefit the participant or the organization to have to fully process a service delivery request, since the participant or requestor has already been successful in advocating for the service. Instead, the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires. We want to note that pursuant to our proposal in § 460.121(d)(2), a service delivery request may be made to any contractor or employee who provides direct care to a participant, and that all individuals providing direct care to participants, whether contractors or employees, should be trained to recognize and receive service delivery requests pursuant to § 460.71(a)(1). However, to specifically limit the exception in § 460.121(e)(2) to requests made to IDT members, where the receiving member of the IDT is able to approve the service delivery request in full at the time the request is made. This will ensure that the IDT remains responsible for determining the benefits a participant should receive, and that contractors or employees, such as a home care aide, are not authorizing services without the IDT's review.

We also believe this exception at § 460.121(e)(2) would reduce the current burden on PACE organizations in three primary ways. First, PACE organizations would not have to bring requests that can be quickly approved by one IDT member to the full IDT for consideration and discussion, which would allow the IDT to use that time for other purposes, including to focus on

requests that require in-depth consideration. Second, because the IDT would not have to conduct a reassessment in each case, we expect that this change would improve the overall speed with which PACE organizations are able to provide necessary services. Third, the IDT would not have to provide separate notification to the participant because the IDT member would inform the participant or requestor that the request was approved in the initial discussion.

Currently the IDT is required to process requests for reassessments from participants and/or designated representatives under § 460.104(d)(2). The IDT is responsible for selecting the appropriate IDT members to conduct the reassessment under § 460.104(d)(2), and for issuing a decision to approve or deny a request under § 460.104(d)(2)(iii). At § 460.121(f), we would require that all service delivery requests, other than those under §460.121(e)(2), must be brought to the full IDT for review and discussion before the IDT makes a determination to approve, deny or partially deny the request. As required by § 460.102(b), each PACE organization's IDT must, at a minimum, be composed of members qualified to fill the roles of 11 disciplines, each of which offers a unique perspective on the participant's condition. CMS commonly refers to this group as the full IDT. Because service delivery requests not processed under § 460.121(e)(2) are processed only for services that cannot be approved in full at the time the request is received, we believe that it is important that the IDT, as a whole, discuss the service delivery request in order to determine whether the request should be approved or denied. A discussion by the full IDT would allow each discipline to offer their perspective on the participant's condition as it relates to the requested service, and ensure that the IDT is best equipped to determine what services are necessary to improve or maintain the participant's health status. As previously discussed, service delivery requests that are approved in full by a member of the IDT at the time the request is made would not have to be brought to the full IDT for review.

In § 460.121(g) we would require that the IDT must consider all relevant information when evaluating a service delivery request. Currently, the regulation is silent on what the IDT must consider when making a decision under § 460.104(d)(2). The IDT must consider, at a

minimum, the findings and results of any reassessment(s) conducted in response to a service delivery request, as well as the criteria used to determine required services specified in § 460.92(b), as discussed in section VI.C. of this final rule. We have seen through our monitoring efforts that certain IDTs do not always consider the reassessments conducted in response to a service delivery request when making a decision. For example, a physical therapist and occupational therapist may both indicate in their discipline-specific reassessments that a participant would benefit from additional home care hours, but the IDT might deny the request without explaining why the recommendations resulting from those reassessments were not followed. We believe it is important that an IDT is able to demonstrate that it took any reassessments performed in the process of reviewing a service delivery request into consideration when making a decision on that service delivery request. Additionally, we believe that IDT decision making for service delivery requests should be aligned with the IDT's decision making for what constitutes a required service under § 460.92(b). Specifically, we believe that a decision by the IDT to provide or deny services must be based on an evaluation of the participant that takes into account the participant's medical, physical, emotional and social needs. We have encountered situations where the IDT made its decision based on one aspect of the participant's condition, for example, their physical health related to their ability to perform activities of daily living, but disregarded other aspects of the participant's condition, such as their medical, emotional, and social needs. We believe that the IDT must consider all aspects of the participant's condition in order to make an appropriate decision. For example, if the participant is requesting to attend the PACE center on additional days due to feelings of social isolation and depression, it would be inappropriate for the IDT to make a decision based on the participant's physical needs without considering their emotional and social needs. Additionally, under the modifications in § 460.92, we would also expect PACE organizations to utilize current clinical practice guidelines and professional standards of care when rendering decisions, as applicable to

a requested service. We discuss this decision making process and use of these guidelines in more detail in section VI.C. of this final rule.

Based on feedback from PACE organizations and advocacy groups, at § 460.121(h) we proposed to require an in-person reassessment only prior to an IDT's decision to deny or partially deny a service delivery request. Currently, the IDT must perform a reassessment as part of its consideration of any request to initiate, eliminate, or continue a service under § 460.104(d)(2), regardless of whether the request is approved or denied. We modified the requirements related to conducting reassessments in response to a participant or designated representative's request to initiate, eliminate, or continue a service in the 2019 PACE Final Rule (84 FR 25644 through 25646). The regulations now permit the IDT to conduct that reassessment via remote technology if certain requirements are met, but the IDT must conduct an in-person reassessment prior to denying a request. However, since that rule was published on June 3, 2019, we have continued to receive feedback from PACE organizations requesting further action to address the burden of conducting reassessments in response to service delivery requests, specifically when the IDT can approve a request without performing a reassessment. Under our proposal, if a service delivery request is brought to the full IDT and the IDT determines that it can approve the request based on the information available, the IDT would not be required to conduct a reassessment of the participant prior to making a decision to approve the service delivery request. We understand that many IDTs have frequent interactions with PACE participants and may be able to make a decision to approve a request without having to conduct another reassessment based on internal consultation and knowledge of the participant. As we indicated in our discussion for § 460.121(e)(2), we do not believe that delaying the provision of a requested service the IDT has determined is necessary, in order to conduct a reassessment, benefits the PACE organization or the participant. We believe the IDT, with its knowledge of the participant, is in the best position to determine if a reassessment is necessary prior to

approving a service delivery request. Therefore, CMS would only require a reassessment prior to the IDT denying or partially denying a request under this proposal.

If, after consideration of all available information, the full IDT expects to make a decision to deny or partially deny a service delivery request, the IDT would be required to perform an unscheduled in-person reassessment pursuant to § 460.121(h)(1), prior to making a final decision. We would consider a request denied or partially denied whenever the IDT makes a decision that does not fully approve the service delivery request as originally requested. For example, if a participant requested 3 hours of home care a week, and the IDT made a decision that the participant only required 2.5 hours of home care each week, such a decision by the IDT would constitute a partial denial because the request was not fully approved as requested by the participant. In other words, any decision to offer a compromise, an alternative service, or to grant only a portion of the request would constitute a partial denial. The in-person reassessment must be conducted by the appropriate members of the IDT, as identified by the IDT, in order to align with the current requirement under § 460.104(d)(2) that the IDT is responsible for identifying the appropriate members to conduct the reassessment. We believe this change would strike an appropriate balance between protecting participants and ensuring that the process for handling service delivery requests is not overly burdensome for PACE organizations.

We also proposed in § 460.121(h)(1) to require that any reassessment conducted for a service delivery request must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs in a manner consistent with § 460.92, and the revisions we proposed to those provisions. We have seen through our monitoring efforts that in conducting reassessments as a result of requests to initiate, eliminate or continue particular services, the IDTs are not always evaluating whether the requested service would actually improve or maintain the participant's condition, taking into account all relevant aspects of the participant's condition, including assessing the participant's medical, physical, emotional and/or social needs as applicable. We believe this information is vital, and must be

considered by the full IDT in making its decision. For example, if a participant is requesting more days at the PACE center for social reasons, the IDT should ensure that the appropriate members of the IDT conduct the reassessment in order to evaluate the participant's social needs, and whether additional center days are necessary to meet the participant's needs, including improving the participant's social condition. We discuss our proposed modifications for § 460.92 in greater detail in section VI.C. of this final rule.

In accordance with our belief that the IDT is in the best position to determine if a reassessment is necessary prior to approving a service delivery request, at § 460.121(h)(2) we proposed that the IDT may choose to conduct a reassessment (via either remote technology or in-person) before approving a service delivery request, but we do not believe we should require one as part of the process for approving service delivery requests. If the IDT determines a reassessment should be conducted prior to approving the request, the IDT would still be responsible for processing the service delivery request, and notifying the participant, in the timeframe specified at § 460.121(i).

In paragraph (i) we would establish a time frame in which the IDT must make its determinations regarding service delivery requests and provide notification of its decisions. The current requirement under § 460.104(d)(2)(iii) states that the IDT must notify the participant or designated representative of its decision to approve or deny a service delivery request as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request, unless the IDT extends the timeframe. CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states "72 hours from the date" and thus requires that the timeframe starts on the day received. We proposed a similar timeframe at § 460.121(i), to require that the IDT make its determination and notify the participant or their designated representative of the determination as expeditiously as the participant's health condition requires, but no later than 3 calendar days after the date the

IDT receives the request. We continue to believe this is a reasonable timeframe for the IDT to discuss the request, conduct reassessments when required, and make a decision.

The IDT is currently allowed to extend the timeframe for notifying a participant or their designated representative by no more than 5 additional days under § 460.104(d)(2)(iv). Extensions are currently permitted when the participant or designated representative requests an extension, or when the IDT documents its need for additional information and how the delay is in the interest of the participant. In § 460.121(i)(1) we proposed to include a similar provision for extensions, which would allow the IDT to extend the timeframe for review by up to 5 calendar days beyond the original deadline in certain circumstances. In § 460.121(i)(1)(i) we proposed that the IDT may extend the timeline for review and notification if the participant or other requestor listed in § 460.121(c)(2) or (3) requests the extension. We would change designated representative to requestor to account for the change we made in § 460.121(c) regarding who can make a service delivery request, and including caregivers in situations where that person may not already be a designated representative. We believe that the participant or other requestor should be able to request an extension. For example, the participant may be out of town and the caregiver may request the IDT to take an extension in order for the participant to be in-person for the reassessment related to the request. Under proposed § 460.121(i)(1)(ii) the IDT could extend the timeframe for review and notification when the extension is in the best interest of the participant due to the IDT's need to obtain additional information from an individual who is not directly employed by the PACE organization, and that information may change the IDT's decision to deny a service. We believe it is important that the IDT does not routinely take extensions when the participant or other requestor has not asked for an extension. We understand that when the IDT has to obtain information from individuals not employed directly by the organization, it may be difficult to get timely responses. We also understand that obtaining this information is beneficial for the IDT and the participant in order to ensure that the IDT has sufficient information to make a decision on whether or not a service should be

approved. For example, if the IDT is considering a request for dentures, information from the participant's dentist would be relevant to the review, and the IDT may need to take an extension if the dentist does not respond within the initial 3 calendar days. However, we believe it is important that PACE organizations develop processes to ensure prompt decisions about service delivery requests, and that IDTs do not routinely or unnecessarily rely on extensions of the notification timeframe, such as when information can be obtained from an employee of the PACE organization. We also proposed, for extensions based on the need for additional information, to apply the requirements currently in § 460.104(d)(2)(iv)(B) which require the IDT to document the circumstances that led to the extension and to demonstrate why the extension is in the participant's interest. We would add a new requirement at § 460.121(i)(2) to require the IDT to notify the participant or the designated representative in writing, as expeditiously as the participant's condition requires but no later than 24 hours after the IDT extends the timeframe, and to explain the reason(s) for the delay. We would require that the notification of the extension must occur within 24 hours from the time the IDT makes the decision to extend the timeframe because we believe it is important that participants or their designated representatives understand that a decision may be delayed and why, especially if the extension was taken by the IDT.

In addition, we proposed adding requirements at § 460.121(j) related to notifying the participant or the designated representative of the IDT's decision to approve, deny, or partially deny a service delivery request. Currently, IDTs are required to notify the participant or their designated representative of the decision to approve or deny a request under § 460.104(d)(2)(iii). As we previously discussed, in relation to our proposals under § 460.121(c), we proposed to expand the number of individuals who can make a service delivery request. However, we did not change the individuals whom the IDT would notify of its decision to approve or deny the service delivery request. We believe that in all circumstances, the participant (or designated representative) should receive the notification of the IDT's decision to approve or deny the

service delivery request. In the rare situation where a caregiver, such as a family member, is not the designated representative, notification of the service delivery request would be sent to either the participant or designated representative, and not the family member. As always, under current § 460.102(f), the PACE organization remains responsible for establishing, implementing and maintaining documented internal procedures that govern the exchange of information between participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e). We would expect that PACE organizations, as a part of that documented process, have a method for determining when notification should go to the participant versus a representative (including a caregiver).

In paragraph (j)(1) we would specify the notification requirements when the IDT approves a service delivery request. Specifically, we would require the IDT to notify the participant or the designated representative of that decision either orally or in writing. We proposed that the notification must explain any conditions for the approval in understandable language, including when the participant may expect to receive the approved service. We believe it is important that the IDT explain to the participant or their designated representative any conditions that may apply whenever the IDT approves a service delivery request. For example, if the IDT is approving a service delivery request for home care, the IDT should indicate the days and hours that are being approved and when the home care would start.

For service delivery requests that can be approved in full at the time the request is made under § 460.121(e)(2), the IDT member who approves the request would be responsible for ensuring that the notification satisfies the requirements in new § 460.121(j)(1). Because a request must be able to be approved in full at the time the participant makes the request under this provision, the IDT member who approves the service would be responsible for providing notification, and ensuring that the conditions of the approval (if any) are explained to the participant. While we allow for the IDT to provide approval notification either orally or in writing, because decisions under § 460.121(e)(2) are made in real time, and communicated to the

participant at the time the request is made, we do not believe written notification would be necessary in these instances; however, a PACE organization may always choose to send written notification following the oral notification in order to memorialize any conditions of the approval.

We also proposed at § 460.121(j)(2) provisions similar to those currently set forth in § 460.104(d)(2)(v), to require that PACE organizations must notify participants or the designated representative of a decision to deny or partially deny a service delivery request both orally and in writing. We believe that the requirement to notify the participant or their designated representative both orally and in writing should be maintained to ensure participants or their designated representatives receive and understand the denial. We also proposed to expand upon the specific requirements for what a denial notice must contain. At §460.121(j)(2)(i) we require that the IDT state the specific reasons for the denial, including an explanation of why the service is not necessary to improve or maintain the participant's overall health status. Under what we proposed, the rationale for the denial would have to be specific to the participant, taking the participant's medical, physical, emotional, and social needs into account, and it would include the results of any reassessment(s) conducted by the PACE organization. The rationale would have to be stated in understandable language so that the participant or designated representative can comprehend why the request was denied. We believe that it is important to continue to require that the IDT provide the specific reasons for a denial. However, based on our experiences monitoring PACE organizations, we believe we needed to propose more detailed requirements about what the explanation of the specific reason(s) for the denial should include. Providing this explanation for a denial would allow the participant or their designated representative to more fully understand why the IDT determined a requested service was not necessary. This would also allow a participant or designated representative to better understand what information they may need to provide if they appeal the denial.

At § 460.121(j)(2)(ii) and (iii), we would retain the requirements currently codified in § 460.104(d)(2)(v)(A) and (B) that the PACE organization inform the participant or designated representative of the right to appeal any denied service delivery request as specified in § 460.122; and that the PACE organization must also describe the process for both standard and expedited appeals, and the conditions for obtaining an expedited appeal. Additionally, with minor modifications, we would retain a requirement similar to current § 460.104(d)(2)(v)(C): the PACE organization would be required to notify Medicaid participants about their right to, and the conditions for, continuing to receive a disputed service through the duration of the appeal. Medicaid participants include all participants that are enrolled in Medicaid only or both Medicaid and Medicare (dually eligible). Currently, § 460.104(d)(2)(v)(C) cross-references all of § 460.122(e), but we believe that a more tailored reference to § 460.122(e) would be preferable. Therefore, we proposed to cross-reference only § 460.122(e)(1) at § 460.121(j)(2)(iv), because the information provided in § 460.122(e)(2) relates to the PACE organization's continued responsibility to continue to furnish to participants all required services other than the disputed service, and is not specifically about continuing to receive the disputed service. We do not believe we need to require that the IDT include information from § 460.122(e)(2) in a service delivery request denial notification because this concept is widely understood and could potentially confuse participants if they received notification of that requirement. However, we solicited comments on whether it would be preferable to retain a cross-reference to all of § 460.122(e).

In § 460.121(k) we proposed to specify the timeframe in which the PACE organization must provide services approved, in whole or in part, through the service delivery request process. We would require the PACE organization to provide the requested service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. We did not propose a specific timeframe due to the many varying types of services that PACE organizations provide. However, we expect PACE organizations to

develop processes to help them identify how quickly they need to provide a service based on the participant's condition. For example, we would generally expect that a drug used to treat a participant's diabetes would be provided much more quickly than we would expect a dental cleaning to be provided. That is because a treatment for diabetes may require a more immediate response, whereas a dental cleaning may not be as urgent. We recognize that not all services can be physically provided in a rapid timeframe, however, we do expect that the PACE organization take prompt action to ensure the approved service is provided as expeditiously as needed. Additionally, for services that can be approved under § 460.121(e)(2), while we require that the IDT member be able to approve the request in full at the time the request is made, we do not require that the approved service be physically provided at the time the request is made. Instead, those approved service delivery requests must also be effectuated under the requirements in this section.

The current requirement at § 460.104(d)(2)(vi) states that the PACE organization must automatically process a participant's request as an appeal when the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care. We would retain this requirement, unaltered, at § 460.121(*l*). We continue to believe that this is an important safeguard for participants to ensure they have access to the appeals process, even when a PACE organization does not adhere to the processing requirements under the rules of this part.

In paragraph (m) we would add requirements that would address record keeping for service delivery requests. While PACE organizations are currently required to document all assessments under § 460.104(f), we believe that it would be important to have a separate section in the new § 460.121 that more specifically addresses the record keeping requirements, to help ensure that PACE organizations accurately document and track all service delivery requests and have a complete and accurate record of each request and how it was resolved. In § 460.121(m) PACE organizations must establish and implement a process to document, track, and maintain

records related to all processing requirements for service delivery requests. We would specify that PACE organizations must account for, and document, requests received both orally and in writing. PACE participants often call PACE organizations and request a service over the phone, and it is important for the PACE organization to have an established process to accurately document and track those verbal requests, along with requests submitted to the organization in writing. Once a PACE organization receives a service delivery request, the PACE organization would be responsible for documenting, tracking and maintaining all records that relate to the processing of the service delivery request, including but not limited to, the IDT discussion, any reassessments conducted, all notification that was provided to the participant or designated representative, and the provision of the approved service, when applicable. These documentation requirements would apply to all service delivery requests, including service delivery requests that can be approved in full at the time the request is made per § 460.121(e)(2). Additionally, as we mention in our discussion of § 460.200(d) at section VI.E. of this final rule, we would require that documentation be safeguarded against alteration, and that written requests for services must be maintained in their original form. We also proposed to require that these records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

Because we proposed toe define the requirements for service delivery requests in the new § 460.121, we also proposed to remove all requirements relating to service delivery requests from the current § 460.104(d)(2). Specifically, we are removing §460.104(d)(2)(i) through (v) and we would modify the existing language in § 460.104(d)(2) to reiterate that the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request. Additionally, as we discussed in § 460.121(h)(2), the IDT may conduct a reassessment as determined necessary for services it intends to approve. We would modify language in § 460.104(d)(2) to direct readers to the new § 460.121(h) for the requirements regarding conducting reassessments in response to service delivery requests.

We summarize the comments received on the proposals related to service delivery requests and provide our responses to those comments below.

Comment: All commenters that addressed this proposal were supportive of moving the requirements for service delivery requests from § 460.104(d)(2) to a new section of the regulations in § 460.121. A few commenters were generally supportive of the provisions related to service delivery requests.

Response: We thank the commenters for their support of the provisions related to service delivery requests.

Comment: A few commenters offered suggestions related to the proposed use of the term "service delivery request". Most suggested that CMS use "service determinations" rather than "service delivery request" because it is more consistent with the objective of this process which is to determine whether a PACE organization should initiate, modify, or continue a service in response to a request from a participant, designated representative, or caregiver. Another commenter recommended using the term "service request" as it is consistent with past practice and suggested that it was easier for participants to understand.

Response: We appreciate the commenters' response to our request for feedback and we are persuaded to make changes to the regulation text and incorporate both of the recommended terms to use the term "service determination request" rather than "service delivery request" for requests that are processed under proposed § 460.121. We anticipate that such a change will help participants and PACE organizations to understand that this process is ultimately about the determination of whether to initiate, modify, or continue a service. After consideration of the comments received, we recognize that there are two actions that largely make up the proposed service delivery request process; the request itself and the determination made by the PACE organization. In order to maximize clarity regarding the process, we are revising the title of new section § 460.121 from "Service delivery requests" to "Service determination process." We believe that this modified title better reflects the process in its entirety and better encompasses

the nature of these actions. We are also revising the remainder of the proposed regulatory text for part 460, where applicable, to reflect this change in terminology. In addition, we will use the terms "service determination request" and "service determination process" when referring to the requirements under § 460.121 in the remainder of this final rule.

Comment: All commenters that addressed the proposal at § 460.121(a) were supportive of the requirement that PACE organizations must have formal written procedures for identifying and processing service determination requests.

Response: We thank the commenters for their support of this provision and are finalizing this requirement as proposed.

Comment: The majority of commenters expressed concern with the proposal at § 460.121(b)(1)(ii) to require PACE organizations to process a request to "otherwise change" an existing service as a service determination request. These commenters agreed with CMS's position that PACE organizations should be responsible for processing requests to change existing services, but believed that requests to change an existing service were more comparable to a grievance that should be addressed under § 460.120, rather than a service determination request because requests of this sort suggest that a participant is dissatisfied with the characteristics of the service. The same commenters also recommended that CMS modify the proposed language at § 460.121(b)(1)(ii) by limiting requests to modify an existing service to include requests to increase, reduce, or eliminate a service.

Response: We thank the commenters for their feedback and recommendations. We disagree that requests to otherwise change an existing service under § 460.121(b)(1)(ii) are better classified as a grievance. A grievance for purposes of the PACE program, is defined in regulation at § 460.120 as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished. Requests that otherwise change an existing service would not be considered a grievance under the current definition. For example, if a participant is currently receiving two hours of home care a day in the morning, but requests to

instead receive those hours in the evening because the participant is physically weaker in the evening and needs more assistance at that time, we would not consider this request a grievance and would expect the organization to process such a request as a service determination request. However, it's possible that a request to modify a service would be both a service determination request and a grievance. For example, if the participant requests their home care hours to be modified but also expresses dissatisfaction with the quality of home care being provided, we would expect the organization to process both a service determination request and a grievance. In addition, there are no regulatory timeframes for processing grievances under § 460.120, and the participant is not afforded appeal rights if a grievance is not fully resolved in their favor. As noted in the proposed rule, we believe that defining service determination requests to include requests to modify an existing service, which includes requests to increase, reduce, eliminate, or otherwise change a particular service, is an important safeguard, as participants may believe that the services they are currently receiving are not sufficient to meet their needs (85 FR 9125). We continue to believe that this is the best way to capture and provide resolution for such requests and therefore we are finalizing this provision as proposed. As a reminder, pursuant to the requirements we are finalizing at § 460.121(e)(2), if a service determination request can be approved in full by a member of the IDT at the time the request is made, the full IDT does not need to consider it, and the PACE organization would not need to conduct a reassessment.

Comment: A commenter agreed with CMS' proposal to limit service determination requests to requests made after the development of the initial care plan. Several commenters recommended that CMS expand the scope of requests that do not constitute a service determination request under proposed § 460.121(b)(2), to include services requested during the semi-annual and change in participant status reassessment and care planning processes, services requested in the course of participants' treatment discussions with PACE IDT members, both during and outside the assessment and care planning processes, and requests for services that are

not appropriate for the treatment of the participants' conditions. Another commenter agreed with expanding the scope of exclusions and suggested that requests made during a semi-annual or unscheduled assessment would necessitate pausing the reassessment and care planning process currently underway and beginning a separate service determination request process. Another commenter recommended limiting requests processed as service determination requests to those requests that occur after the completion of a required initial, semi-annual, or change in status assessment and requests that a participant or designated representative makes when they are not in agreement with the care plan at the end of any individual encounter with an IDT member.

Response: We agree that routine treatment discussions and discussions that occur during the assessment and care planning process are instrumental in determining the services necessary to meet a participant's needs. However, we also strongly believe that the recording, processing, and tracking of service determination requests is an essential beneficiary protection which ensures PACE participants' access to necessary care and services, and provides participants an avenue to appeal adverse decisions. As proposed, there is an exception at § 460.121(b)(2) for requests to initiate, modify or continue a service, made prior to the development of the initial care plan. We continue to believe that this is appropriate and are not expanding the scope of this exclusion. We do not believe that it would be in a participant's best interest to exempt requests for services made during semiannual or unscheduled reassessments required under §§ 460.104(c) and (d)(1) or during the care planning processes described in §§ 460.104(e) and 460.106(d) from the service determination process because the relevant regulations do not specify timeframes for these processes. Absent regulatory timeframes, these processes frequently take a long time to resolve and if a service determination request made as part of those processes were exempted from the proposed requirements for service determination requests, these requests could take an unacceptably long time to resolve. For the same reason, we also believe that requests for services made during treatment discussions with PACE staff, including members of the IDT and others, should be processed as service determination requests. Through CMS monitoring and

oversight, we have noted cases of non-compliance with the existing requirements at §460.104(d)(2) governing the documentation and processing of participant requests, and the provision of approved services. We believe it is important that all requests that satisfy the definition of a service determination request be processed using the process we proposed. As stated in the proposed rule (85 FR 9126), we decided that requests made during the course of treatment discussions should constitute service determination requests in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service determination requests and those that do not.

CMS would like to clarify that the exception to the definition of "service determination request" for requests made prior to the development of the initial care plan at § 460.121(b)(2) includes requests made during the initial care planning process under §§ 460.104(b) and 460.106(a). We recognize that the regulation text as proposed, which permits this exception "if the request is made prior to development of the initial care plan", may have caused confusion because this could be interpreted to mean that a participant or other requestor could make a service determination request during the development of the initial plan of care but prior to the completion of the initial plan of care. This was not our intent. As noted in the proposed rule (85 FR 9125), this exception would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased), and we continue to believe that this approach would be beneficial to the participant and the PACE organization as it is during this process that the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. In order to avoid confusion regarding when this exception would apply, we are modifying the proposed regulatory text at § 460.121(b)(2) in a manner consistent with our proposal, to emphasize our intent that this exception would apply to all requests for services made prior to completion of the development of the initial plan of care. As revised, the text of § 460.121(b)(2) will state

"Requests to initiate, modify or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care".

Comment: Comments on CMS' proposal to allow caregivers to make service determination requests at § 460.121(c)(3) were varied. A few commenters agreed with the proposal at § 460.121(c)(3) to allow caregivers to make service determination requests, and one commenter noted that allowing caregivers to request services on behalf of a participant may increase the involvement of caregivers and distribute the burden of transmitting provider or prescriber recommendations to the IDT. However, the majority of commenters expressed concern with this proposal, which would expand the individuals who can make a service determination request to include caregivers. These commenters suggested that this may result in requests from a large number of individuals who do not have legal authority to speak on behalf of the participant, requests that are inconsistent with the wishes of the participant and designated representative, requests that may be motivated by financial or personal gain, and increased administrative burden on PACE organizations in processing these requests. These commenters suggested that the involvement of multiple caregivers could negatively impact PACE organizations' ability to respond to the wishes of the participant or their designated representative(s), for example in regard to end-of-life care decisions. These commenters noted that it is important that the PACE organization and the IDT remain focused on the wishes of the participant, either expressed directly or through their designated representative. These commenters also stated that including caregivers, which is not a term defined in regulation text, among the individuals who are able to request service determinations on behalf of participants may have unintended, negative consequences. The commenters noted that although a caregiver or family member who has not been identified as a designated representative would not be able to make service determination requests under the existing regulatory framework, they would not be prevented from providing input related to a participant's care under §460.102(d)(2)(ii) and §460.106(c)(2). With regard to requests that are personally motivated, the commenters

suggested that this change would permit an individual living in a participant's home who might lose housing if the participant moved to a nursing home to request home modifications or additional in-home services to permit the participant to remain at home despite the fact that those requests could be inconsistent with the wishes of the participant or their designated representative and prior determinations by the IDT that the participant cannot remain safe in the home. These commenters strongly recommended that requests for service determinations could only be made by participants or their designated representatives, stating that the term designated representative has been interpreted by PACE organizations to be either a legal representative or a representative identified according to the PACE organization's policy who is authorized to act on behalf of the participant. Additionally, all of these commenters recommended modifying the plan of care requirements in § 460.106(e) to replace the term caregiver with the term designated representative.

Response: We thank commenters who supported this provision and appreciate the feedback related to permitting caregivers to make service determination requests. While we believe the designation of a representative is important, the PACE regulations do not require or describe any specific formal process for designating a representative, nor do they require PACE organizations to develop such a process. As discussed further, in section VI.D. of this final rule related to service delivery, in response to comments, CMS confirms that the IDT may take into consideration informal support when developing the participant's plan of care. Specifically, the IDT may consider care provided by willing and able caregivers when determining what necessary services will be provided by the PACE organization, either directly or through its contractors. Given the fact that caregivers may provide some care to participants, we believe that it is equally important that caregivers are able to advocate for services on a participant's behalf. It is important that these individuals have an avenue to request services for a participant, especially when caregivers that had actively been providing care are no longer willing or able to provide care in the manner they had been. For example, if a caregiver was providing overnight

supervision to a participant, but is no longer willing or able to provide that care due to the participant's increased dementia, the caregiver should be able to submit a service determination request to the PACE organization. In regard to commenters' concerns relating to the potential increase in burden on PACE organizations related to the proposal to permit caregivers to make service determination requests, we believe most PACE organizations currently allow caregivers to make these requests. According to data submitted by PACE organizations for auditing purposes from 2017 through 2019, approximately 50 percent of service determination requests were made by participants and 30 percent were made by caregivers or other family members. Because organizations are already accepting and processing requests from caregivers (as these data show), we do not anticipate that modifying the regulation in this way would result in a significant influx of requests for PACE organizations. In addition, the role of caregivers in PACE participants' lives has been recognized in CMS's policies regarding the PACE program since the first PACE interim final rule was published in 1999 (64 FR 66249), and caregivers play a vital role in the development and reevaluation of the plan of care as we noted at VI.A. of the preamble of this final rule.

We would like to state that nothing in this provision would expand which individuals may be considered a caregiver, nor is it meant to imply that any person in the participant's life may request services. As we noted in the preamble to the 2006 PACE rule (71 FR 71284), a caregiver is a person who attends to a participant's needs and has a caregiving relationship with the participant. Historically, CMS has not included employees or contractors of the PACE organization, such as providers or prescribers, as "caregivers" under this definition, and instead has interpreted this term to include less formal support providers such as family members. This is consistent with our discussion at 71 FR 71284 which stated that CMS uses the term "family member" and "caregiver" interchangeably. Employees and contractors of PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominantly financial incentive to provide care; we have not considered these individuals to be

"caregivers" under the regulations. PACE organizations are already required at § 460.106(e) to involve a participant's caregiver or caregivers for purposes of care planning. We believe that those individuals, who should already have a relationship with the PACE organization, should also be able to advocate for services outside of the care planning process. We believe that permitting caregivers to make service determination requests on behalf of a participant is an important safeguard: those participants who do not have a designated representative may rely on a caregiver to advocate for services on their behalf, and caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For the same reasons, we also do not agree with the commenters' recommendations to exclude caregivers from the care planning process at § 460.106(e). Additionally, caregivers have been involved in the care planning process under PACE since the regulations were implemented in 1999 through the interim final rule and CMS has never previously received feedback indicating that this practice might be problematic. As we gain more experience with caregiver service determination requests, we may take further action as appropriate; for example, to further refine our position on who may be considered a caregiver for purposes of making service determination requests.

With regard to requests that may be motivated by financial or personal gain, we believe that the proposed service determination process would prevent these types of personal conflicts of interest from negatively impacting participants. The IDT is responsible for deciding whether to approve or deny a service determination request, and thus functions as a gatekeeper preventing the provision of unnecessary services. Section 460.121(g) also requires the IDT to consider all relevant information when evaluating a service determination request, including the criteria specified in § 460.92(b). Under § 460.92(b), the IDT must consider the participant's current medical, physical, emotional, and social needs, and current clinical practice guidelines and professional standards of care applicable to the particular service, when deciding to provide or deny a service. Additionally, if the IDT conducts a reassessment in response to the service

determination request, the reassessment should take into consideration the participant's wishes and preferences for care, to ensure that services, if approved, are in the participant's best interest, in accordance with the participant's rights for participation in treatment decisions under § 460.112(e). If a service determination request is made and the IDT determines, after reassessing the participant, that the service is not necessary based on all relevant information, the IDT should deny the request. These requirements would apply to all requests for services, including requests for end of life care. For example, a caregiver may request palliative care for the participant, but the IDT would need to consider all relevant information prior to approving or denying the service, including the participant's and designated representative's wishes, applicable clinical guidelines, and the participant's current medical, physical, emotional, and social needs. Similarly, if a caregiver requested the participant to remain in the home for self-serving purposes, and the IDT determined that the participant was not safe to remain in the home and did not wish to remain in the home, the IDT should not approve the caregiver's request.

Therefore, we believe that the IDT plays a pivotal role in ensuring that services are provided only when necessary, and this in turn protects participants from receiving services that are not in their best interest, including those that may be motivated by financial or personal gain.

Comment: Several commenters provided feedback related to permitting prescribers or other providers to make service determination requests. One commenter was in favor of permitting prescribers or other providers to make service determination requests on behalf of a participant. Most commenters were opposed to CMS allowing other individuals to make service determination requests. These commenters noted that PACE organizations, through the participant's primary care provider, are currently required to oversee the use of specialists. In situations when another provider or prescriber's recommendation is not implemented, the IDT would be required under proposed § 460.102(d)(1)(ii) to document the reasoning behind this determination in the participant's medical record. One commenter noted that for these reasons, this contemplated proposal would be duplicative of the proposed regulatory requirements under

§ 460.102(d)(1)(ii), and as a result would be disruptive to the effective functioning of the IDT. Further, the commenters noted that a participant or his or her designated representative has the right to submit a service determination request if the PACE organization does not provide a recommended service.

Response: We appreciate the commenters' feedback and recognize that by finalizing our proposals at § 460.102(d)(1)(ii), we will enhance the consideration and documentation of recommendations made by specialists, and better integrate those individuals into the process of determining what care and services are necessary for participants. As discussed in section VI.C.3 of this final rule and in response to other comments received, we are finalizing the proposal at § 460.102(d)(1)(ii), largely as proposed. While we continue to believe that communication among specialists and the IDT is vital, we agree with commenters that these communications do not need to be handled through the service determination process. By requiring that the IDT document such recommendations in the medical record in accordance with § 460.210(b), including proposed §§ 460.210(b)(4) and (b)(5), if there is a subsequent service determination request made by a participant, designated representative, or a caregiver, there will be a record of the recommendation and why it was not provided. We expect that this information will provide useful perspective to the IDT and will allow the IDT to conduct a more meaningful review of the service determination request under § 460.121(g). We also agree with the commenter that a participant, designated representative, or caregiver could make a service determination request for any service that was not provided in accordance with a recommendation from an employee or contractor of a PACE organization. Because of these proposals and the integral role the IDT plays in determining what services are necessary, we do not believe that it is necessary to specifically include prescribers or other providers among the individuals who are allowed to submit service determination requests at this time. Accordingly, we are finalizing our proposals for § 460.121(c)(3) as proposed.

Comment: Commenters were supportive of CMS's proposal to allow service determination requests to be made either orally or in writing.

Response: We thank the commenters for their support of this provision.

Comment: Some commenters agreed with CMS's proposal at § 460.121(d)(2) which would allow service determination requests to be made to any employee or contractor of the PACE organization that provides direct care to a participant. The majority of these commenters responded to CMS's request for feedback on whether this requirement should be limited to a smaller subset of individuals and agreed that CMS should limit the individuals to whom a service determination request could be made to a PACE organization's employees and contractors who provide direct participant care in the participant's residence, the PACE center, and while transporting participants, which would preclude service determination requests from being made to direct care providers with whom participants would generally have less frequent contact, for example, hospital staff or other medical specialists. These commenters also suggested that requests for services made while participants are being transported should be limited to routine transportation and exclude transportation in emergency situations. Another commenter recommended limiting request submission to any employee or contractor who serve in a required interdisciplinary team member role to eliminate any confusion for participants, their designated representatives, and employees and contractors of the PACE organization on the process of submitting service determination requests.

Response: We appreciate the commenters' support for this provision. After consideration of the comments received, we will specify in the final rule that service determination requests may be made to any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants. These are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, often on a daily basis. Therefore, we believe that these are the most logical settings where service determination

requests are most likely to occur. It would also be a smaller subset of employees and contractors for the PACE organization to train and oversee to ensure those individuals were correctly identifying service determination requests when they are made. We note that a participant's residence would include a skilled-nursing facility or long-term care facility and a participant would be able to make a service determination request to staff who provide direct care to a participant in those facilities. We also recognize that if we were to finalize this requirement as proposed it could be difficult for a PACE organization to operationalize because of the varied and significant roles played by contractors in PACE. For example, PACE organizations routinely contract with hospitals and it would be difficult to train all of the employees within the hospital system to recognize and accept service determination requests.

In terms of requests made while transporting participants, we do not believe that it is necessary or appropriate to exclude transportation in emergency situations from this requirement. Under the requirements at § 460.70(a), a PACE organization is required to have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services. Because the requirement at § 460.121(d)(2) would only apply to an employee or contractor of the PACE organization, this requirement would not apply to those situations where the PACE organization does not have a contractual relationship for emergency services, including emergency transportation. Additionally, based on our oversight and monitoring experience we have never seen circumstances where a service determination request was made while a participant was being transported for emergency purposes; therefore, we do not expect that this will happen with significant frequency. More commonly, we would expect requests to be made during routine transportation services, and the PACE organization would be required to implement processes for staff and contracted employees to identify and process these requests. However, to the extent that service determination requests are made during emergency

transportation, to a contractor of the PACE organization, we believe it is important for those requests to be captured and processed accordingly.

With regards to commenters' recommendation that requests only be submitted to interdisciplinary team members, we do not believe that this would be in the participant's best interest based on the nature of the care provided by a PACE organization. As discussed in the proposed rule, PACE organizations are required to provide care across all care settings and a participant may not know with whom they need to communicate in order to make a service determination request (85 FR 9127). Certain participants may also see home care aides more frequently than members of the IDT and we believe it is appropriate to permit individuals to communicate service determination requests to home health aides rather than requiring them to make such requests to a member of the IDT. Because of the vulnerability of the PACE participant population, we believe it is important to have a robust system of safeguards in place so that participants have the ability to easily request and obtain access to those services that would improve or maintain their overall health status. We believe that requiring a participant or other requestor to go to a member of the IDT would create an unnecessary hurdle and could lead to confusion, if for example, an individual is instructed by an employee or contractor of a PACE organization to make requests in a different manner.

Comment: A commenter agreed with the proposal at § 460.121(e)(1) which would require the PACE organization to bring a service determination request to the interdisciplinary team as expeditiously as the participant's health condition requires, but no later than 3 calendar days from the date the request is made. Other commenters recommended that CMS change the proposed timeframe for bringing a service determination request to the IDT from 3 calendar days to 3 business days. These commenters were fully supportive of CMS's perspective that there is an acceptable period of time between when the service determination request is made and when it is received by the IDT; however, noted that implementing a 3 calendar-day timeframe will effectively force PACE organizations to convene full IDT meetings on both Fridays and

Mondays to consider requests for services initiated on Thursdays and Fridays. The commenters also noted that holidays that fall on Mondays may pose a challenge if requests must be brought to the IDT within 3 calendar days from the day the request is received. The majority of commenters also recommended CMS change the proposed timeframe for notification in paragraph (i) from 3 calendar days to 3 business days.

Response: We appreciate the commenters' concerns regarding the 3 calendar day timeframes that we proposed for processing service determination requests; however, we disagree with the commenters and consider this to be a reasonable timeframe. Section 1894(b)(1)(B) of the Act requires PACE organizations to provide necessary covered items and services 24 hours per day, every day of the year. PACE organizations must therefore be able to process requests efficiently and timely, even on weekends and holidays. Under the current requirements at § 460.104(d)(2)(iii), the IDT must generally notify a participant or designated representative of its decision to approve or deny a request within 72 hours from the date the request is received. As we stated in the preamble to the proposed rule (85 FR 9129), CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states "72 hours from the date." We stated that we believe this is a reasonable timeframe for the IDT to conduct these reviews, and therefore proposed a similar timeframe in the proposed rule. We believe that requiring the IDT to notify the participant or their designated representative of its decision as expeditiously as the participant's health condition requires, but no later than 3 calendar days at § 460.121(i) provides the IDT sufficient time to meet and make a decision regarding a participant's care, taking into account weekends and holidays, and are finalizing this requirement as proposed. Additionally, we created a second timeframe at § 460.121(e) to ensure that PACE organizations bring requests to the IDT for review within a reasonable period of time. Specifically, we proposed to require that requests must be brought to the interdisciplinary team as expeditiously as the participant's condition

requires but no later than 3 calendar days from the time the request is made, and we believe this timeframe is appropriate for purposes of § 460.121(e). We believe that this timeframe strikes an appropriate balance between providing sufficient time for PACE organization staff to transmit the request to the IDT, while ensuring timely resolution of participant requests. We are therefore finalizing this timeframe as proposed.

Comment: The majority of commenters requested that if CMS finalizes the proposed requirement at § 460.121(d)(2) which would allow for participants to make service determination requests to individuals other than IDT members, that CMS also allow for service determination requests made to non-IDT members to be brought to the appropriate IDT member and that the IDT member have the opportunity to approve the request subject to the streamlined requirements set forth under § 460.121(e)(2). The commenters noted that by adopting this approach, the need for a full-IDT review as required under § 460.121(f) would not be based on who received the request but the nature of the request. The commenters stated that they would not want the additional step of allowing a non-IDT member to bring a service determination request to the appropriate IDT member to lengthen the service determination process overall and recommended that service determination requests be brought to the appropriate IDT member in time for him or her to consider the request and, if approved, notify the participant or his or her designated representative of the approval within the 3 calendar timeframe proposed at § 460.121(e)(1). The commenters stated that this approach would be consistent with CMS' objectives for § 460.121(e)(2), as noted in the proposed rule, "the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires." (85 FR 9128). The commenters further suggested that consistent with CMS' observations in regard to proposed § 460.121(e)(2), the recommended approach would also reduce the current burden on PACE organizations.

Response: The exception that we proposed at § 460.121(e)(2) provided that if a member of the IDT receives a service determination request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. This provision was intended to allow for immediate approval of a service determination request during a conversation between a participant or their designated representative or caregiver and a member of the IDT. Allowing an employee or contractor of a PACE organization who is not an IDT member to communicate the request to the appropriate IDT member for approval would require the non-IDT employee or contractor to identify the appropriate member of the IDT that should receive the request, which could take several days and would take away from the immediacy of the approval. We intended to create an exception to expedite the process for approval of service determination requests, and reduce unnecessary burden on the PACE organization, given the fact that PACE organizations, as direct care providers, routinely interact with participants and these interactions often include treatment discussions that may result in a service determination request by the participant. We do not anticipate that finalizing this requirement as proposed would create a large burden on PACE organizations because, if a member of the interdisciplinary team would have been able to approve a particular service determination request in full at the time the request was made, we presume that in the event the same service determination request was brought to the full IDT, the full IDT would also have the ability to quickly approve the request at that time, without having to conduct a reassessment. Based on these considerations, we are not modifying this requirement and are finalizing this provision as proposed.

Comment: Commenters were supportive of the proposal at § 460.121(e)(2), which would allow a member of the IDT to approve a service determination request in full at the time the request is made and not be required to follow certain processing requirements. Specifically, this would exclude the requirements at proposed § 460.121(f) through (i), (j)(2), and (*l*) which

include review by the full interdisciplinary team, reassessment in response to a service determination request, and notification timeframes.

Response: We thank the commenters for their support of this provision.

Comment: The majority of commenters agreed with the proposed provisions at § 460.121(g) which set forth the specific information the IDT must consider when evaluating a service determination request.

Response: We thank the commenters for their support of this provision.

Comment: Several commenters were also in favor of the proposal at § 460.121(h), which would require that if the IDT expects to deny or partially deny a service determination request, the appropriate members of the IDT, as identified by the IDT, must conduct an in-person reassessment before the IDT makes a final decision, and that the team members performing the assessment must evaluate whether the requested service is necessary to meet the participant's needs. These commenters requested clarification on whether assessments can be completed in advance of the IDT's receipt of the request, so long as the assessment is completed in response to the request.

Response: We thank the commenters for their support of this provision. With respect to assessments being completed in advance of the request being brought to the full IDT, we wish to clarify that this would be acceptable provided the regulatory requirements, including § 460.121(h), are satisfied. However, we would not expect this to occur often. As required under § 460.121(h)(1), if the IDT expects to deny or partially deny a request, the appropriate member of the IDT, as identified by the IDT, must conduct an in-person reassessment before the IDT makes a final decision. Given the 3 calendar day timeframe for a PACE organization to bring a service determination request to the IDT under § 460.121(e)(1), there may be situations when one or more members of the IDT are able to conduct a reassessment in response to a service determination request in order to gather the relevant information needed for discussion and review by the full IDT within that timeframe. However, there is a risk that the appropriate

member of the IDT, as identified by the IDT, may not participate in a reassessment if the reassessment is completed prior to the IDT convening. This fact notwithstanding, if the reassessment was completed in response to a service determination request, and when the full IDT meets, the IDT determines that the assessment was conducted by the appropriate IDT members, this would be permitted.

Comment: Several commenters expressed concern that the proposed criteria that must be met for the IDT to extend the 3 calendar day timeframe for review and notification of a service determination request at § 460.121(i)(1) is overly restrictive. The commenters also recommended revising the proposed requirements under § 460.121(i)(1) to allow for extensions when a participant is not available for an assessment or when an IDT member is unexpectedly not available. The commenters explained that in addition to situations in which the requestor may request an extension of the 3-day timeframe, it is also possible that the participant may be unavailable for a reassessment that is required for the IDT to make its determination. These commenters suggested, for example that the participant may be out of town or otherwise unavailable for reasons beyond the PACE organization's control and rather than requiring the requestor to request an extension in these situations, the IDT should, on its own, be able to notify the requestor of the need for an extension beyond 3 days. The commenters also recommended that CMS not limit the extension timeframe at § 460.121(i)(1) to 5 days when the participant or their designated representative requests an extension for a longer period of time. Further, the commenters stated that while they agree it is important that the IDT does not routinely take extensions when the participant or other requestor has not requested one or the participant is unavailable for a required reassessment, the proposed language in § 460.121(i)(2) does not take into account circumstances that necessitate such extensions. Specifically, it is possible that the IDT member identified by the IDT as needing to perform a reassessment or who is critical to the IDT's discussion of the service determination request is unexpectedly not available. In situations when the PACE organization can demonstrate the importance of this reassessment and/or the

IDT member's participation in the IDT discussion and the potential for it to change the IDT's decision to deny a service, and that the circumstances surrounding the IDT member's absence could not be anticipated, the commenters argue that an extension of up to 5 business days is appropriate. They expressed their belief that extending the timeframe for notification of the service determination request would be preferable to exceeding the standard 3-day timeframe and then having to automatically process the service determination request as an appeal which would further delay the requestor's receipt of a response to his/her request.

Response: We appreciate the commenters' concerns and agree that there may be situations that arise during the course of the service determination process that would hinder a PACE organization's ability to make its decision and notify the participant or their designated representative of its decision within the required timeframes under § 460.121(i). In the proposed rule (85 FR 9129), we accounted for situations where the participant or other requestor should be able to request an extension under § 460.121(i)(1)(i) and used as an example circumstances where the participant is out of town and stated that the caregiver could request the IDT take an extension in order for the participant to be in-person for the reassessment required for the request. We would encourage the IDT to discuss service determination requests with the participant where the IDT needs to perform a reassessment and the participant would be out of town. Because decisions related to service determination requests must be made as expeditiously as the participant's condition requires, we do not believe that it would be appropriate to allow for any additional extensions beyond the proposed 5 calendar day timeframe. If the IDT is unable to conduct a reassessment within that timeframe, then we would expect that the IDT would issue a denial and subsequent appeal rights. We reiterate in this final rule that it is important that the IDT does not routinely take extensions when the participant or other requestor has not solicited it because of the frailty of the PACE population. We also note that that any extension must be documented in accordance with the recordkeeping requirements at § 460.121(m).

With respect to the recommendation that CMS allow for extensions when an IDT member is unexpectedly not available, we do not believe that it would be appropriate to view this as justifying an extension. The requirements at § 460.121(i) specify that the IDT must make its decision and provide notification of that decision as expeditiously as the participant's condition requires but no later than 3 calendar days after the date the IDT receives the request and we do not believe that it would be appropriate for an extension to be taken for a reason unrelated to the participant's availability or condition. It is the responsibility of the PACE organization to ensure that there is sufficient staff coverage to meet these requirements.

Comment: The majority of commenters agreed with the proposed provisions at § 460.121(i)(2), which would require an IDT to notify the participant or their designated representative in writing as expeditiously as the participant's condition requires but no later than 24 hours after the IDT decides to extend the timeframe under § 460.121(i)(1), and explain the reasons for the delay. However, these commenters also recommended modifying the requirement to allow PACE organizations to notify the participant or designated representative of the extension either orally or in writing. The commenters suggested that regardless of whether the notification is oral or in writing it would include an explanation of the reason(s) for the delay and would be issued no later than 24 hours after the IDT decides to extend the timeframe. They also noted that allowing oral notification would facilitate the requestor's receipt of notice of the extension, because if CMS required PACE organizations to issue written notification within 24 hours after the IDT decides to extend the timeframe, it would require at least a day or two for such written notification to reach the requestor. Additionally, regardless of whether notification was provided orally or in writing, commenters noted the PACE organization would have to maintain documentation of the notification in accordance with the recordkeeping requirements at § 460.121(m).

Response: We appreciate the commenters' suggestions to modify the proposed regulatory text at § 460.121(i)(2) to allow PACE organizations to provide notification of the

decision by the IDT to extend the regulatory timeframe either orally or in writing. We believe that providing written notification of the rationale for an extension is important in order to ensure the participant receives a full explanation. Additionally, a written explanation of the extension will allow the participant to share that information with family members or caregivers if desired, for instance if the participant needs assistance with understanding the rationale. Therefore, we are not persuaded to modify the regulation at this time to allow PACE organizations to notify participants orally instead of in writing, and are finalizing the requirements under § 460.121(i)(2) as proposed. We will consider building additional flexibility into the regulation through future rulemaking. Additionally, while we are not modifying the regulation to allow for oral notification and PACE organizations will be required to provide written notification when the IDT extends the timeframe for processing a service determination request, nothing would preclude the organization from choosing to call a participant in addition to sending a written notification. This would alleviate any concerns the organization might have about providing notice to the participant in as timely a manner as possible.

Comment: The majority of commenters agreed with CMS's proposal to require PACE organizations to provide the participant or designated representative with oral or written notice of the IDT's decision to approve a service determination request under § 460.121(j)(1). However, these commenters also requested clarification regarding CMS' expectations with respect to the requirement that such notice must explain the conditions of the approval.

Response: We appreciate the commenters' support. The explanation of the conditions of an approval that the IDT is required to provide to the participant or their designated representative under § 460.121(j)(1) should include any parameters that may be applicable to the approval. We wish to clarify that PACE organizations would only be required to explain the conditions of the approval if the request is approved in full, but there are conditions applicable to the approval. As we discussed in the proposed rule, requests are not considered approved in full unless the IDT member can approve exactly what is requested. (84 FR 9127). In these situations,

if there are conditions on a particular service that are not inconsistent with a participant's request but that the IDT still needs to make the participant aware of, we would expect that they notify the participant of the conditions of the approval that apply. These conditions may include any additional information about duration or timing, or a limitation on the service that needs to be conveyed to the participant. For example, if a participant makes a general service determination request for physical therapy (and does not request a specific duration), and the PACE organization approves physical therapy, but determines that the participant only needs physical therapy 3 times a week for 6 weeks, the required notice must include the specific duration and frequency of the approved service. Another example would include circumstances where the PACE organization approves a visit to a specialist, but requires the participant to go to a particular contracted specialist, the required notice must include this information. If the request cannot be approved in full as requested, then the decision is a partial denial and the specific reason for the denial and appeal rights must be provided both orally and in writing pursuant to § 460.121(j)(2). For example, if the participant makes a service determination request for 8 hours of home care, split over 3 visits each week, but the PACE organization approves a total of 6 hours of home care, split between 2 visits each week, this would be considered a partial denial and notification would have to be provided pursuant to § 460.121(j)(2). Another example would be if a participant requested physical therapy for six weeks, but the PACE organization only approved physical therapy for four weeks. Because the PACE organization did not approve exactly what the participant requested, and only approved four weeks instead of six, that decision would be considered partially denied.

Comment: The majority of commenters agreed with CMS' proposed provisions in § 460.121(j)(2), which require PACE organizations to provide the participant or designated representative with oral and written notice of the IDT's decision to deny or partially deny a request. We proposed that this notification must include the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health

status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language, inform the participant or their designated representative of his or her right to appeal the decision under § 460.122, describe the standard and expedited appeals processes, and inform a Medicaid participant of his or her right to continue receiving disputed services during the appeals process and the conditions for continuing to receive disputed services. One commenter recommended that CMS provide PACE organizations with template language for denial notifications.

Response: We thank the commenters for their support of this provision. Historically we have not been prescriptive about PACE organizations' appeals processes, and it remains up to the PACE organization to develop a formal written appeals process with specified timeframes for response to address noncoverage or nonpayment for services under § 460.122(a), subject to the minimum requirements specified in § 460.122(c). Accordingly, we believe that each PACE organization is in the best position to create a notice that is tailored directly to its internal processes, in accordance with the requirements at § 460.122(j). We appreciate the commenters' recommendation and we may consider providing template language for denial notifications in the future, as appropriate in light of the needs of the PACE program.

Comment: In response to CMS' request for feedback on whether it would be preferable for § 460.121(j)(2)(iv) to cross-reference § 460.122(e) or § 460.122(e)(1), the majority of commenters agreed that CMS should cross-reference § 460.122(e)(1). Several commenters requested confirmation that the provisions in § 460.121(j)(2)(iv) would not prohibit a PACE organization from informing all participants, regardless of Medicaid eligibility, of their ability to continue receiving disputed services during the appeals process until issuance of the final determination.

Response: We appreciate the commenters' responses to our request for feedback and are finalizing the cross reference at § 460.121(j)(2)(iv) as proposed. At this time the requirement at § 460.121(j)(2)(iv) applies only to Medicaid eligible participants, including those participants

that are dually eligible for Medicare and Medicaid, and we are not expanding this to include Medicare-only participants in this rule. PACE organizations are not required under § 460.122(e) to continue to furnish the service(s) under dispute during the appeals process for Medicare-only participants. The requirements under § 460.122(e)(1) specify that for a Medicaid participant, the PACE organization must continue to furnish the disputed services until issuance of the final determination if the PACE organization is proposing to terminate or reduce services currently being furnished or if the participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

Comment: Commenters agreed with CMS' proposal at § 460.121(k) regarding the effectuation requirements when the IDT approves a service determination request, in whole or in part. As proposed, § 460.121(k) would require PACE organizations to provide approved services as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. This provision would also require the IDT to explain when the participant may expect to receive the service in accordance with § 460.121(j)(1). Commenters also agreed with CMS's proposals under §460.121(*l*) relating to the effect of failure by the IDT to meet the processing timeframes. CMS proposed to require the PACE organization to automatically process an appeal in accordance with § 460.122 if the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, as this failure would constitute an adverse decision.

Response: We thank the commenters for their support of these provisions and are finalizing as proposed.

Comment: Commenters were also supportive of the proposed recordkeeping requirements at § 460.121(m), which would require PACE organizations to establish and implement a process to document, track, and maintain records related to all processing

requirements for service determination requests received both orally and in writing, and ensure those records would be available to the IDT to ensure that all members remain alert to pertinent participant information.

Response: We thank the commenters for their support of this provision and are finalizing as proposed.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes at §§ 460.121(e), (g), (h), (i), (j), (k), (*l*), and (m) as proposed. We are finalizing the remaining provisions at § 460.121 with several modifications. First, we have modified the terminology used at § 460.121 by changing the title to refer to "service determination process" and replacing the term "service delivery request" with "service determination request" throughout. We have also made corresponding changes throughout the proposed regulatory text at part 460. We are amending proposed § 460.121(a) by changing the word "section" to "Part" in order to state that PACE organizations' written procedures for identifying and processing service determination requests must be developed in accordance with the requirements in part 460 rather than § 460.121. This change will better reflect the content of our proposals under § 460.121, which specifically reference other applicable requirements in Part 460 of Title 42 and will not affect the meaning of the regulation as proposed or described in the final rule. We have made modifications to 460.121(b)(2) by changing the language from "made prior to the development of the initial care plan" to "prior to completing the development of the initial plan of care" to reflect our intent, as expressed in the preamble to the proposed rule, that this exception applies until the initial plan of care is complete. We are also amending proposed § 460.121(d)(2) to require that individuals may make service determination requests to any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants, in response to comments received about whether we should adopt an approach that permits service determination requests to be made only in those settings. In

addition, at § 460.121(f) we proposed to use a question mark at the end of the paragraph title instead of a period. This was an oversight and therefore, we have modified the regulatory text to reflect this change. This change will not have a substantive impact on the effect of the regulation. Finally, we have made minor grammatical corrections to § 460.121(b)(1), (c), and (f) which will not change the intended meaning of the regulation as proposed or described in this final rule. We are finalizing the changes at § 460.104(d)(2) as proposed, except in regard to the use of the term "service determination request."

B. Appeals Requirements under PACE (§§ 460.122 and 460.124)

As discussed previously, sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act require PACE organizations to have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. In the preamble to Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) interim final rule which was published in the **Federal Register** on November 24, 1999 (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule), CMS explained that we considered the appeals requirements under what is now MA when creating the appeals requirements for PACE (see 64 FR 66257 and 66258). CMS established the requirements for PACE organizations' appeals processes in §§ 460.122 (PACE organization's appeals process) and 460.124 (Additional appeal rights under Medicare or Medicaid). Over time, PACE organizations have requested that CMS explain certain aspects of the appeals processes described in §§ 460.122 and 460.124. Therefore, we proposed certain changes to §§ 460.122 and 460.124 that would provide additional detail about the appeals process and help ensure consistency in the administration of the appeals process among PACE organizations. We also proposed a few other changes to increase beneficiary awareness of and access to the appeals process, and to align with other changes in this rule. The term "appeal" is currently defined in § 460.122 as a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. We would add a sentence after the definition to

require that PACE organizations must process all requests to initiate, modify or continue a service as a service delivery request before processing an appeal under § 460.122. As we discussed in section VI.A. of this final rule, we have seen through audits that some PACE organizations will process an appeal instead of processing a service delivery request when a participant makes a request to continue receiving a service that the PACE organization is discontinuing or reducing. We would add a sentence to this introductory paragraph in order to affirmatively require that all requests that satisfy the definition of a service delivery request under § 460.121(b) must first be processed as such before a PACE organization may process an appeal. Section 460.122(b) currently provides that upon enrollment, at least annually thereafter, and whenever the IDT denies a request for services or payment, the PACE organization must give a participant written information on the appeals process. Consistent with the changes to existing § 460.104(d)(2) and new § 460.121, which are discussed in section VI.A. of this final rule, we would modify § 460.122(b) to specify that PACE organizations must provide participants with written information on the appeals process at enrollment, at least annually thereafter, and whenever the IDT denies a service delivery request or other request for services or payment. By proposing this change, CMS was seeking to ensure that participants consistently and timely receive information about their appeal rights, including when PACE organizations deny their service delivery requests.

Section 460.122(c) provides requirements for the minimum written procedures that PACE organizations must establish for their appeals process. We have heard that these requirements have created confusion among PACE organizations, which has led to inconsistent implementation among PACE organizations and a lack of participant awareness of and participation in the appeals process. As a result, we proposed a number of changes to decrease confusion and increase beneficiary awareness of and access to the appeals process.

We proposed two modifications at paragraph (c)(2). First, we would add a participant's designated representative as someone who has the right to appeal on the participant's behalf. We

believe that this is an important participant safeguard because it allows for assistance in navigating the appeals process. Additionally, in developing procedures for how a participant or a participant's designated representative files an appeal, PACE organizations would be required to include procedures for receiving oral and written appeal requests. Because of the comprehensive nature of the care PACE organizations provide, participants are likely to have more verbal interactions with staff of the PACE organization and may express their desire to appeal a decision, but may be unsure or confused as to how. We believe that by requiring PACE organizations to accept appeal requests made both orally and in writing, we would create an important safeguard for the participant population enrolled in the PACE program. By allowing both oral and written requests for appeals, this proposal would enhance participant access to the appeals process, and to services covered under the PACE benefit.

Second, in response to questions received from PACE organizations, we would add language in paragraph (c)(4) to specify the qualifications required of an appropriate third party reviewer or members of a review committee. Specifically, we would require PACE organizations to ensure appeals are reviewed by an appropriate reviewer or committee. This includes separating the requirements that an appropriate third party reviewer and the members of a review committee must be "independent" and "appropriately credentialed" to emphasize the fact that an appropriate third party reviewer or member of a review committee must be both independent and appropriately credentialed. We discuss the use of a review committee in the preamble to the 2006 PACE final rule (see 71 FR 71302) and PACE organizations currently utilize review committees in their review processes; therefore, we would incorporate review committees in regulation at this time and require the members of review committees to satisfy the same requirements as appropriate third party reviewers. Employees or contractors of a PACE organization may participate in review committees as long as they meet the requirements set forth in § 460.122(c)(4). Consistent with the current requirements at § 460.122(c)(4), we would specify that in order to be an appropriate third party reviewer or member of a review

committee, an individual must be an impartial third party who was not involved in the original action and does not have a stake in the outcome of the appeal. We also proposed to add language that more clearly defines an appropriately credentialed reviewer. As we discussed in the preamble to the 2006 final rule, the appropriate third party reviewer must be someone with expertise in the appropriate field. Thus it would not be appropriate for a social worker to review an appeal related to a physical therapy denial; nor would it be appropriate for a gynecologist to review a denial of services relating to coronary surgery (71 FR 71302). Therefore, we would modify the language in paragraph (c)(4) to specify that an appropriate third party reviewer is one who is credentialed in a field or discipline related to the appeal. We do not believe that these proposals would affect the way PACE organizations currently choose their third party reviewers since the existing regulation at § 460.122(c)(4) requires the appointment of an appropriately credentialed and impartial third party that was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal. By proposing amendments to expressly state that the same requirements also apply to the members of a review committee, we believe that as proposed this would give PACE organizations more clarity and flexibility to utilize resources within the organization as well as contracted employees.

PACE organizations have expressed confusion about the third party review process, and we are aware of inconsistent decisions made by third party reviewers, such as inconsistent decisions at different PACE organizations. In order to reduce confusion, create a more consistent application of Medicare and Medicaid coverage requirements under PACE, and increase consistency for participants, we proposed additional modifications to the requirements under § 460.122(c). Specifically, we added a new paragraph (c)(5) that would require PACE organizations to take specific steps to ensure their third party reviewers understand the PACE benefit package and the coverage requirements under the PACE program, and how to review requests in a manner consistent with both. As noted in the preamble to the 2006 PACE final rule (71 FR 71302), PACE organizations should ensure that credentialed and impartial third party

reviewers are trained to make decisions in a manner similar to the determinations under section 1862(a)(1)(A) of the Act. Such determinations would be based on the participant's medical needs and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors. Therefore, we proposed, in new paragraph (c)(5), to require PACE organizations to provide written or electronic materials to an appropriate third party reviewer(s) that, at a minimum, explain that services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98, the need to make decisions in a manner consistent with determinations made under section 1862(a)(1)(A) of the Act, and the requirements in § 460.90(a) that specify that many of the limitations on the provision of services under Medicare or Medicaid do not apply in PACE.

The requirements for providing appeal notifications at § 460.122(d) currently provide that a PACE organization must give all parties involved in the appeal (1) appropriate written notification and (2) a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing. However, PACE organizations have expressed that this section of the regulation is confusing because it discusses both the notification requirements and the participant's opportunity to submit evidence during an appeal. To reduce confusion, we would separate these requirements. Accordingly, we would redesignate paragraph (g) as (h) and also change the title of paragraph (h) to "Actions following a favorable decision." This redesignation allows for the addition of new paragraph (g) that sets forth notification requirements. We would modify paragraph (d) to address the existing requirement that the PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing. At new paragraph (g), we proposed to revise the notice requirements for appeals to more closely align with the notice requirements for service delivery requests at § 460.121(j) by specifying the content of the notice in order to ensure consistency and minimize confusion for PACE organizations and participants. PACE organizations would be required to give all parties involved in the appeal (for example participants or their designated

representatives) appropriate written notice of all appeal decisions. In the case of appeal decisions that are favorable to the participant, the PACE organization would be required to explain any conditions on the approval in understandable language. For partially or fully adverse decisions, the PACE organization would be required to state the specific reason(s) for the denial, explain the reason(s) why the service would not improve or maintain the participant's overall health status, inform the participant of his or her right to appeal the decision, and describe the additional appeal rights under § 460.124. Conditions of approval may include, but are not limited to, the duration of the approval, limitations associated with an approval such as dosage or strength of a drug, or any coverage rules that may apply. We also proposed to revise and move the current requirements at paragraph (h) into new paragraph (g)(2)(ii). These requirements specify that for determinations that are wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify CMS, the State administering agency, and the participant. Because this paragraph includes additional notification requirements that PACE organizations must follow after a decision is made to deny an appeal, we believe that this belongs in § 460.122(g)(2) for notice of adverse decisions. We would revise this requirement to use terminology consistent with our other amendments to § 460.122, specifically, to refer to "partially or fully adverse" decisions and to refer to an appeal decision rather than to a determination for consistency with § 460.122(g)(2)(i) and other sections of this regulation.

We proposed a few minor changes to align with other changes in this rule. First, we would change the reference to § 460.104(d)(2)(iv) in § 460.122(c)(1) to reference the service delivery request requirements in § 460.121(i) and (m). The current citation references the extension requirements for unscheduled reassessments; however, we believe that this reference should have been to the general timeframes for processing service delivery requests. We would redesignate the current paragraphs (c)(5) and (6) as (c)(6) and (7) in § 460.122 to allow for the addition of a new paragraph (c)(5), as discussed earlier in this section.

Lastly, we added language to § 460.124 that delineates the additional appeal rights that PACE participants are entitled to receive under Medicare or Medicaid and add processing requirements for the PACE organization. In response to comments CMS received on the 1999 PACE interim final rule, CMS discussed stakeholder concerns about the PACE appeals process in the preamble to the 2006 PACE final rule and reiterated the intended process in the preamble. (See 71 FR 71303 and 71304.) Specifically, CMS stated in the preamble to the 2006 PACE final rule that Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible participants have access to the State Fair Hearing (SFH) process (see 71 FR 71303). However, despite this clarification, CMS's audits have revealed that PACE organizations continue to misinterpret the requirements under § 460.124 relating to participants' additional appeal rights under Medicare or Medicaid. To address this issue, we proposed several changes to § 460.124. First, we would add new paragraphs (a) and (b) at § 460.124. In § 460.124(a) we would specify that Medicare participants have the right to a reconsideration by an independent review entity (IRE). We recognize that there are differences in the terminology used in PACE versus MA and therefore have to add similar language at new § 460.124(a)(1), (2), and (3) to establish in regulation the requirements for how an appeal may be made to the independent, outside entity, the timeframe in which the independent outside entity must conduct the review, and who are the parties to the appeal. In § 460.124(a) introductory text and (a)(1) we have intended to parallel the requirements at § 422.592(a) with minor differences. Under MA there is automatic escalation to the independent review entity at this level of appeal if the organization upholds its adverse decision, in whole or in part. However, in PACE, appeals are not automatically escalated because most PACE participants are dually eligible for Medicare and Medicaid benefits and these participants may choose to utilize the Medicaid or Medicare route for independent review. For these dually eligible individuals, it may be more appropriate to pursue an appeal through the Medicaid path rather than the Medicare path. The provisions relating to automatic-escalation in

MA ensure that the beneficiary receives a review by an independent reviewer; however, this protection is not necessary in PACE as the PACE participant has already received an independent review on the appeal during the internal appeal processed in accordance with § 460.122. Therefore, we proposed at § 460.122(a)(1) to specify that a written request for a reconsideration must be filed with the independent review entity within 60 calendar days of the decision by the third party reviewer. We did not specify who must file the request because we discuss at § 460.124 that the PACE organization must assist the participant in choosing which appeal rights to pursue (that is, Medicaid SFH or Medicare IRE) and as such, we believe that the PACE organization is also responsible for ensuring that the request is filed with the appropriate external entity. However, a participant always maintains the right to file a request without assistance from the PACE organization. At § 460.124(a)(2) we would add a requirement that the independent review entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract. The independent review entity is currently operating under these timeframes, consistent with the requirements at § 422.592(b), and participants are currently utilizing the independent review entity to exercise their external appeal right, consistent with CMS's historical interpretation that these requirements are applicable to the PACE program. We also proposed adding language at § 460.124(a)(3) that would parallel the requirement at § 422.592(c), to specify that when the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization. We are seeking to enhance transparency and we believe it is important to make PACE organizations aware that they are considered a party to the appeal once it reaches the independent review entity. We would add a new paragraph (b) that specifies that Medicaid participants have the right to a SFH as described in part 431, subpart E. Finally, we would add a new paragraph (c) to specify that participants who are dually eligible for both Medicare and Medicaid have the right to external review by means of either the IRE or the SFH process. This provision would specify

that dually eligible participants may choose to pursue an appeal through either the Medicare or Medicaid process. In accordance with the existing provisions under § 460.124, PACE organizations must assist dual eligible participants in choosing which route to pursue if both the IRE and the SFH review processes are applicable. For example, if the appeal is related to an enrollment dispute, the Medicaid SFH process would be the appropriate route for a participant to pursue. Whereas for a dispute related to a Part D medication, the IRE would be the appropriate route for a participant to pursue. By codifying these appeal rights in regulation, we are seeking to enhance transparency for PACE organizations to ensure that participants are able to access additional levels of appeal in order to receive services they believe that they are entitled to under the PACE benefit.

We summarize the comments on the proposals related to appeal requirements under PACE, and provide our responses to those comments, below.

Comment: Numerous commenters agreed with the proposed changes to the definition of "appeal" under § 460.122, which the commenters' noted would specifically state their understanding of CMS's longstanding policy, that a service determination request must be processed before an IDT determination regarding a request to initiate, modify, or continue a service could be appealed. Another commenter recommended revising the definition to eliminate the language "a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions or termination of services" and instead replace it with "a participant or their designated representative's action taken with respect to the PACE organization's denial of a service request to initiate, continue, increase, decrease or discontinue a service." The commenter suggested that this would eliminate any confusion on what constitutes an appeal.

Response: We appreciate commenter support of our changes to the definition. While we proposed adding a sentence to the introductory language of § 460.122 to require that PACE organizations process any request to initiate, modify, or continue a service as a service

determination request before the PACE organization can process an appeal under § 460.122, we did not propose any changes to the current language regarding what constitutes an appeal. We have chosen not to include the designated representative in the definition because we specifically provide at § 460.122(c)(2) that a PACE organization's appeals process must include written procedures for how "a participant or their designated representative files an appeal…", we do not believe it is necessary to refer to the designated representative in the introductory text. Furthermore, we do not believe it is necessary to change the proposed definition as the commenter suggests since we are maintaining the proposed criteria for what constitutes a service determination request to include requests to initiate, modify, or continue a service. Therefore, we are finalizing our proposed changes to the introductory text of § 460.122 as proposed.

Comment: The majority of commenters recommended that CMS modify the proposed language in § 460.122(b) from, "or other request for services or payment" to "or request for payment." These commenters expressed confusion about why CMS would include "or other services" in addition to a service determination request. A commenter stated that "or other request for services or payment" is in reality a service determination request and therefore is redundant in § 460.122(b) and should be removed.

Response: Section 460.122(b) does not address the right to appeal, but rather the responsibility of the PACE organization to provide participants with written information about their appeal rights. In addition to providing notice of these rights at enrollment and annually, we believe that it is important for the PACE organization to provide notice when it denies a service determination request, which is why we proposed to modify § 460.122(b) to include that language. We did not propose to make other changes to the text of § 460.122(b) such as removing "or other requests for services or payment." We agree with commenters that all requests for services would be resolved within the service determination request process. Because all requests for services would be resolved through the service determination request process, there would be no "other requests for services" that might be subject to appeal, and

removing this language would not substantively affect the meaning of the revised text of § 460.122(b) as proposed. However we also note that certain requests for payment may not meet the definition of a request to initiate, modify or continue a service. For example, a PACE participant may go to the hospital or emergency room without first requesting the service from the IDT, and may subsequently submit the bill to the PACE organization as a request for payment. Since the underlying service was already received, this would not be a request to initiate, modify or continue a service, but we would expect the PACE organization to provide notification of appeal rights if the payment was denied by the IDT. We can also envision scenarios where a participant receives a bill for routine care provided by a contractor of the PACE organization, such as care provided by a nursing facility or specialist, and the participant subsequently requests payment from the PACE organization. Because these services would not involve requests to initiate, modify, or continue a service, these payment decisions would be processed outside of the service determination process. For these reasons, we are persuaded to remove "or other request for services" but will retain "or payment" as this would align with our proposal to require notification of appeal rights following a denied service determination request or a decision to deny a request for payment for a service. We are therefore revising § 460.122(b) to remove the reference to "other services" and to require that upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment, the PACE organization must give a participant written information on the appeals process.

Comment: The majority of commenters recommended modifying the cross-reference in § 460.122(c)(1), "Minimum requirements", from § 460.121(g) to § 460.121(i) as it would make the appeals requirement clearer.

Response: We appreciate the commenters' recommendation and agree that this cross-reference should be revised. In section VI.B. of the proposed rule, we proposed in § 460.122(c)(1) to change the reference from § 460.104(d)(2)(iv) to §§ 460.122(i) and (m) to

reference both the notification timeframes and the documentation requirements for service delivery requests. (85 FR 9133). The proposed regulation text at § 460.122(c)(1) incorrectly referenced § 460.121(g). Therefore we have modified the regulatory text in this final rule to reflect the correct reference, to §§ 460.121(i) and (m).

Comment: The majority of commenters agreed with the revisions at § 460.122(c)(2), to require that a PACE organization's appeals process must include written procedures for how a participant or their designated representative files an appeal. The commenters specifically noted their support for allowing the participant's designated representative as an individual who may submit an appeal on the participant's behalf.

Response: We thank the commenters for their support of this provision.

Comment: We received several comments on the proposed requirements for third party reviewers. The majority of commenters supported the requirements that allow for third party review by a committee at § 460.122(c)(4). The commenters also supported the requirement that a third party reviewer or committee member must be appropriately credentialed in the field or discipline related to the appeal. A commenter specifically recommended requiring that appeals of physical therapy services be reviewed by a licensed physical therapist. These commenters also supported the proposed provisions at § 460.122(c)(5), which require distribution of written or electronic materials to third party reviewers.

Response: We thank the commenters for their support of these provisions. With respect to the comment regarding review by licensed physical therapists, we expect that the PACE organization would determine what constitutes an appropriately credentialed individual in the field or discipline related to the appeal as specified at proposed § 460.122(c)(4)(i). Given the vast array of services that could be under appeal, we do not believe it would be feasible for CMS to list each discipline or set of appropriate credentials that we would expect to see in each case. Therefore, we are not adopting this suggestion. In section VI.B. of the proposed rule, we provided an example stating that it would not be appropriate for a social worker to review an

appeal related to a denial of physical therapy services, and we would expect a PACE organization to consider this guidance when making determinations about whether third party reviewers are appropriately credentialed in the field or discipline related to the appeal.

Comment: The majority of commenters recommended that CMS either clarify the meaning of, "all parties," as referenced in § 460.122(d) and § 460.122(g) by adding a list of individuals that would be considered a "party", or modify the language to state, "A PACE organization must give the participant or designated representative..." These commenters also recommended adding designated representative as a party that must be provided information on the PACE organization's appeals process in § 460.122(b).

Response: The use of the terminology "all parties" is consistent with the current language used in the context of appeal notification and the opportunity to present evidence at § 460.122(d) and we proposed to retain the existing language. According to Merriam-Webster.com, the term "party" includes "a person or group taking one side of a question, dispute, or contest."[75] Generally, we would interpret the term "all parties" to refer to all parties taking a formal position on one or the other side of the appeal, which would include the participant (and his or her designated representative, if applicable), and the PACE organization. This terminology has been in use in the PACE regulations since 1999 and based on CMS oversight activities we do not have concerns with how PACE organizations are currently interpreting this term. Under § 460.122(c)(2) a participant may file an appeal, or a participant's designated representative may file an appeal on the participant's behalf. If a designated representative has filed an appeal on behalf of a participant, that representative typically acts on the participant's behalf throughout the appeal process, and CMS considers the participant and the designated representative to be the same "party" for purposes of the appeal. For purposes of notification at § 460.122(g), the "parties" to the appeal will depend on the circumstances of the appeal. Generally, we believe the parties would include the participant or the designated representative

[75] https://www.merriam-webster.com/dictionary/party

of the participant, if applicable. For example, if a participant filed an appeal without assistance from a designated representative, the PACE organization would be required to provide notification to the participant, but if the participant designated a representative to represent him or her in the appeal, the designated representative should also receive notice. For purposes of submitting evidence during the appeal at § 460.122(d), there may be circumstances where a representative submits evidence on behalf of the participant, and there may be circumstances where both the participant and the representative submit evidence during the appeal. After consideration of the comments received, we are finalizing this provision as proposed.

With respect to the recommendation to add the designated representative as a party that must be provided information about the PACE organization's appeals process under § 460.122(b), we do not agree that this is necessary, although there may be circumstances when a designated representative should receive information about the appeals process. As we discussed earlier in this section, the PACE organization would be required to give a participant written information on the appeals process upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment. A participant could designate a representative for purposes of interacting with the PACE organization at any one of these points in time, in which case the notice to the participant could go to the designated representative who is acting on the participant's behalf. Additionally, we proposed to retain the current requirements for notification of an adverse decision in regard to a service determination request, which provide that a PACE organization must notify the participant or the designated representative orally and in writing of the adverse determination, in a notification that includes a description of both the standard and expedited appeals processes § 460.121(j)(2).

Comment: A commenter was supportive of the proposed notification requirements at § 460.122(g). The majority of commenters recommended revising the language in § 460.122(g)(2) to remove the statement, "the PACE organization must provide the participant

with written notification of the decision," since the requirement to notify participants is already contained in the first paragraph of § 460.122(g). These commenters also recommended removing the newly redesignated § 460.122(i). The commenters noted that the requirements to notify CMS and the State administering agency of a wholly or partially adverse decision in the newly redesignated § 460.122(i), are incorporated into § 460.122(g)(2)(ii) and are therefore duplicative.

Response: We thank the commenters for their support and for their recommendations. We recognize that the proposed language at § 460.122(g)(2) restates the requirement to provide written notification of the decision to the participant; we are persuaded to revise this section to remove the duplicative language. At § 460.122(g), we proposed that a PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal. We did not refer to "all parties" at § 460.122(g)(2) and we realize that this could be viewed as inconsistent. Therefore, we are removing the language at § 460.122(g)(2) that states that a PACE organization must provide the participant with written notification of the decision. By making this change we are enhancing consistency and also ensuring notification to all parties involved in the appeal. Because the designated representative is permitted to file an appeal on a participant's behalf, and therefore are parties to the appeal, we believe it is important that any notification, including one related to a partially or fully adverse decision, be communicated to all parties involved.

With regards to removing the redesignated § 460.122(i) (existing § 460.122(h)), we agree that the requirements to notify CMS and the State administering agency of a wholly or partially adverse decision in the redesignated § 460.122(i) would be duplicative of the notification requirements in proposed § 460.122(g)(2)(ii). It was not our intention to duplicate these requirements in the regulations and therefore we are revising the amendatory language to the regulation text to redesignate the current paragraph (h) as a new paragraph (g)(2)(ii), as revised.

Comment: A commenter agreed with CMS's proposal at § 460.122(g) which sets forth the requirements for providing notification of appeal decisions. The majority of commenters requested clarification regarding the proposed requirements in § 460.122(g)(2)(ii), which would require PACE organizations to provide written notification of an adverse appeal decision to the participant, CMS and the State administering agency (SAA) at the same time the decision is made. Specifically, the commenters sought to clarify the meaning of "at the same time the decision is made" and how long organizations would have to notify CMS and the SAA.

Response: We appreciate the commenter's support of this provision. With respect to the commenters' question regarding what CMS intends by the language "at the same time the decision is made," we appreciate the opportunity to share our historical interpretation of this requirement. Under the current requirements at redesignated § 460.122(c)(6), the PACE organization's appeals process must include written procedures for responses to and resolution of appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the PACE organization receives the request. Under the current requirements at §§ 460.122(f)(1) and (f)(2), a PACE organization must also have an expedited appeals process and must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal, unless the PACE organization takes an extension under § 460.122(f)(3). While both the decision and notification must be made within these regulatory timeframes, we recognize that generally the decision for an appeal will occur prior to the notification (sometimes by more than a day). Additionally, under the current requirements at § 460.122(h) (redesignated as § 460.122(g)(2)(ii)), the PACE organization must notify CMS, the State administering agency, and the participant of a determination that is wholly or partially adverse to a participant, at the same time the decision is made. We have not historically expected PACE organizations to notify CMS and the SAA of a decision at the same time as the decision is made; rather, our historical interpretation has been that notification to those entities should occur around the same time as when the PACE organization notifies the

participant of the adverse decision. We would expect that organizations notify CMS and the SAA of the adverse decision at the time they notify the participant of the adverse decision, or within the regulatory timeframe for notification pursuant to §§ 460.122.

We are removing "participant" from the list at § 460.122(g)(2)(ii) because including that term on the list would be duplicative in light of the change to the wording of that provision. The requirement at § 460.122(g) already establishes that the PACE organization must give all parties involved in the appeal, which includes the participant (or, as applicable, his or her designated representative), appropriate written notification of the decision to approve or deny the appeal. Therefore, we believe that removing participant from the list of entities that must also receive notification of a denial or partial denial at § 460.122(g)(2)(ii) will reduce confusion without affecting the substance of our proposals.

Comment: A commenter addressed the proposals at § 460.124 and was supportive of the additional clarifications around additional appeal rights under Medicare and Medicaid.

Response: We thank the commenter for their support of this proposed provision and therefore are finalizing as proposed.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to the introductory text of § 460.122, § 460.122(c)(2), (c)(4), (c)(5), (d), (h), and § 460.124 as proposed. We are finalizing the provisions at § 460.122(b) with modifications. Specifically, we have modified the requirement at paragraph (b) by removing the language "other requests for services". We are finalizing the provision at paragraph (c)(1) with a minor technical correction to change the reference from § 460.121(g) to §§ 460.121(i) and (m). We are finalizing § 460.122(g) as proposed, with a few technical changes to address duplicative language. First, we removed duplicative language in paragraphs (g)(2)(i) and (g)(2)(ii) stating that the requirements in question applied to decisions that are partially or fully adverse, and added "partially or fully" in paragraph (g)(2) to reflect the fact that all of the requirements within (g)(2) applied to decisions

that were partially or fully adverse to the participant. We also removed language from paragraph (g)(2)(i) that restated the requirement at (g) that the PACE organization must provide the participant with written notification of its decision. Similarly, at paragraph (g)(2)(ii) we have removed several references to "the participant," including from the list of people who must receive notification of a partially or fully adverse decision, to reflect the fact the participant would already receive notice of any decision under § 460.122(g), as a party to the appeal. In addition, there was an oversight in the proposed amendatory language for the regulation text that would reflect the move of the current requirements at paragraph (h) into new paragraph (g)(2)(ii), as proposed at 85 FR 9133. Therefore, we are modifying the amendatory language to reflect this change.

C. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§ 460.92, 460.96, and 460.102)

1. Required Services

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act state that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[76] CMS codified these required services in § 460.92 of the regulations, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered items and services, all Medicaid covered items and services, as

[76] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

specified in the State's approved Medicaid plan, and other services determined necessary by the interdisciplinary team (IDT) to improve and maintain the participant's overall health status.

We proposed to modify the requirements at § 460.92 to more clearly define required services, and to specify CMS' expectations for making decisions about the services that are required under the PACE benefit package. First, we would create a new paragraph (a) and include under (a) the current requirements in § 460.92. In order to do that, we proposed to renumber existing paragraphs (a), (b), and (c) as (a)(1), (2), and (3). We would add a new paragraph (b) that provides the standards that the IDT must consider when evaluating whether to provide or deny services described under (a) for a participant.

In addition to redesignating § 460.92(a) as § 460.92(a)(1), we would modify the language to refer to all Medicare-covered services. In light of our amendments to the definition of "services" in § 460.6, and the current definition of that term, PACE organizations should understand that providing necessary drugs, whether they are covered under Medicare Parts A, B, or D, is an important part of the PACE benefit package. See section VI.I. of this final rule for a more detailed discussion of the definition of "services."

We would add a new paragraph (b) in order to specify the standards that the IDT must consider when evaluating whether to provide or deny services required under § 460.92(a) for a participant. Under § 460.92(b)(1) we would require the IDT to take into account all aspects of a participant's condition, including the participant's medical, physical, emotional, and social needs, when determining whether to approve or deny a request for a service. As we discussed in section VI.A. of this final rule, the determination for a service should be based on all aspects of the participant's care. For example, additional center days may not be necessary when considering the participant's physical needs, but when taking into account the participant's social needs, the IDT may find that those services become necessary in order to improve the participant's social or emotional condition. We have discovered through audits that PACE organizations sometimes only consider the medical or physical needs of a participant but do not

consider their social or emotional needs when those social or emotional needs are relevant to the request.

We also proposed to add language at § 460.92(b)(2) that would require organizations to utilize current clinical practice guidelines and professional standards of care when making a decision, so long as those guidelines and standards are applicable to the particular service. PACE organizations are currently required to utilize current clinical practice guidelines and professional practice standards when developing the outcome measures for their quality improvement programs at § 460.134(b). When we discussed this requirement in the preamble to the 1999 PACE interim final rule, we stated that we expect that PACE organizations will utilize current clinical standards as a routine part of their daily operations and care management strategies. (See 64 FR 66260). However, we have discovered through our PACE audits that decisions to deny services are sometimes not based on accepted clinical guidelines or standards. We understand that current clinical practice guidelines and professional standards of care may vary based on the type of service that is being considered. For example, when determining if a participant requires a cardiac catheterization, the organization may reference clinical practice guidelines issued by the American Heart Association. On the other hand, when determining the appropriate insulin for a participant the organization may appropriately refer to guidelines published by the American Diabetic Association. We also understand that certain services may not have an applicable clinical practice guideline. For example, determining the frequency of PACE center attendance may not be based on clinical practice guidelines, but may instead be based on the medical, physical, emotional, and social needs of the participant. Therefore, we added language to (b)(2) to require the IDT to take into account current clinical practice guidelines and professional standards of care if applicable to a particular service. By adding this requirement, we do not intend to restrict a PACE organization's ability to determine what service is appropriate or necessary for a participant: the IDT would remain responsible for determining

the participant's overall health status and needs, and ensuring those needs are met through the provision of necessary services.

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to utilize current clinical practice guidelines as a part of their quality improvement program, and they are required to consider the participant's physical, medical, emotional and social needs as a part of care planning discussions. We believe that by modifying this provision we will not be increasing burden on PACE organizations, as they already consider these items on a routine basis.

We summarize the comments on the proposals related to required services, and provide our responses to those comments, below.

Comment: All commenters that addressed this provision recommended that CMS modify the proposed language at § 460.92(b) to state, "The interdisciplinary team makes determinations of whether or not to approve, deny or partially deny services for participants. These determinations must be based on an evaluation of the participant that takes into account...". These commenters asserted that this modification is necessary based on the proposed removal of § 460.96(a) and they believed the revised language would clarify the IDT's authority to approve or deny services. These commenters also agreed with removal of § 460.96(a), contingent on CMS' use of the recommended language in § 460.92(b).

Response: We thank the commenters for their recommendation regarding the establishment of the IDT's authority to make decisions. As we stated in the preamble to the proposed rule, the IDT's authority and responsibilities are defined throughout the PACE regulations, and under our proposal the IDT would retain the its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Therefore, our proposal would retain the IDT's ability to make decisions to approve or deny services consistent with the proposed regulatory requirements at § 460.92(a). 85 FR 9136. As proposed, the introductory language at §

460.92(b) states "Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section...." Paragraph (a) of section 460.92 encompasses the complete PACE benefit package including all Medicare-covered services and all Medicaid-covered services, as specified in the State's approved Medicaid plan.

We believe that commenter's proposed change to "the interdisciplinary team makes determinations" was suggested in order to ensure that the IDT's authority to render these decision was clear. However, we believe our proposed introductory language at § 460.92(a) appropriately articulates this authority. We would also reiterate that decisions made under 460.92(b) encompass all decisions made by the IDT and are not limited to service determination requests processed under 460.121. We do not believe that the commenters' recommendation would significantly clarify the IDT's authority to make decisions regarding what services will be approved or denied.

After consideration of the comments received, we are finalizing our changes to § 460.92 as proposed, without modification.

2. Excluded Services

As we stated earlier in this section, in the discussion regarding required services, the PACE benefit package includes all Medicare-covered items and services, all Medicaid-covered items and services, as specified in the state's approved Medicaid plan, and other services determined necessary by the IDT to improve or maintain the participant's overall health status. The regulations at § 460.96 list a number of services that are excluded from coverage under PACE. Currently, paragraph (a) states that any service that is not authorized by the IDT, even if it is a required service, is an excluded service unless it is an emergency service. In addition, paragraph (b) states that in an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental are also excluded from coverage under PACE unless

specifically authorized by the IDT as part of the participant's plan of care. We proposed to remove § 460.96(a) and (b).

These proposals are consistent with our authority to amend the regulations. The exclusions in § 460.96 are not specifically listed in the PACE statute. They were included in the 1999 PACE interim final rule that implemented the PACE program in part because they were included in section A.6 of the PACE Protocol included as Addendum A to the 1999 PACE interim final rule. (See 64 FR 66247 and 66301 and subparagraphs 1894(f)(2)(A) and 1934(f)(2)(A) of the Act.) Sections 1894(f)(1) and 1934(f)(1) of the Act give the Secretary the authority to issue regulations to carry out the PACE program created under sections 1934 and 1894 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that, in issuing such regulations the Secretary shall, to the extent consistent with the provisions of sections 1894 and 1934 of the Act, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol. As we stated in the 2019 PACE final rule (84 FR 25613), we believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[77] which has now been replaced by the PACE program agreement.[78] Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements under sections 1894 or 1934 of the Act, but precludes the Secretary from modifying or waiving any of the following provisions:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive integrated acute and long-term care services.
- The IDT approach to care management and service delivery.

[77] https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf
[78] https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf

• Capitated, integrated financing that allows the PACE organization to pool payments received from public and private programs and individuals.

• The assumption by the PACE organization of full financial risk.

Taking this authority into account, we would remove § 460.96(a) for the following reasons. CMS has gained a significant amount of experience with the PACE program since the 1999 PACE interim final rule, and we now believe that a number of PACE organizations are interpreting the exclusion under § 460.96(a) in a manner that is not consistent with sections 1894 and 1934 of the Act. Many PACE organizations appear to be interpreting § 460.96(a) to allow an IDT to exclude from coverage any service that the IDT does not authorize for a participant, even if it is clearly covered under the Medicare or Medicaid programs and is medically necessary. For example, CMS has identified through audits that some PACE organizations have denied certain types of covered Part D drugs for participants, even when the drug is medically necessary and the participant is qualified to receive the drug under Medicare.

These denials are inconsistent with the statutory requirement under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act to provide all items and services covered by Medicare and Medicaid, as well as all additional items and services specified in regulations. As we stated in the 2006 PACE final rule (71 FR 71248), in accordance with sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. PACE organizations are required to provide all Medicare covered services and all Medicaid covered services in accordance with the State's approved Medicaid plan under current § 460.92(a) and (b). In addition, PACE organizations are required to cover other items and services that are determined necessary by the IDT to improve and maintain the participant's overall health status under current § 460.92(c). In order to ensure that IDTs continue to make decisions that are consistent with the statutory requirements, we

would remove paragraph (a) from § 460.96. We believe that removing paragraph (a) is necessary in order to ensure that participants receive the services to which they are entitled under PACE.

By proposing to remove paragraph (a), we did not intend to waive or eliminate the IDT approach to care management and service delivery. The IDT's authority and responsibility are defined throughout the PACE regulations, and under this amendment, the IDT would retain its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Additionally, as discussed in our changes to § 460.92, the IDT's decision to provide or deny required services must be based on an evaluation of the participant that takes into account the participant's current medical, physical, emotional and social needs, along with any current clinical practice guidelines and professional standards of care that are applicable to the particular service. We do not believe that the current provision at § 460.96(a) affects an IDT's authority for determining what services are required under § 460.92, or changes the IDT's responsibility for coordinating 24-hour care delivery. However, we are concerned that the current language at § 460.96(a) is confusing and implies that there are some required services that are not covered under the PACE program because they are excluded. The term "excluded" implies that a service is outside of the benefit package or never covered. The term "excluded" could also suggest that services that are not authorized are not appealable, which runs counter to our historical interpretation of the PACE statutes and regulations and the policies we have promulgated to safeguard participants' right to appeal adverse decisions by the IDT. While the IDT remains responsible for determining the needs of each participant, and then implementing services that would meet those identified needs, PACE participants should always have the ability to advocate for services, through the service delivery request and appeal process, including any services the IDT determines not to be necessary (or does not authorize).

We would eliminate paragraph (b) from § 460.96 for the following reasons. Currently, this paragraph generally excludes from PACE coverage private rooms and private duty nursing services, and non-medical items for personal convenience, in an inpatient facility, but notes that a private room or private duty nursing services would be covered if medically necessary, and non-medical items for personal convenience would be covered if specifically authorized by the IDT as part of the participant's plan of care. We continue to believe that services such as a private room, private nursing services, or non-medical personal care items would not be covered under PACE, unless they were medically necessary or authorized by the IDT as part of the participant's plan of care. However, we believe that including this provision under a section of the regulation titled "Excluded Services" may give a false impression that the IDT would not have to consider whether those services are medically necessary or necessary to improve and maintain the participant's overall health status. As we previously indicated, the IDT is responsible for comprehensively assessing each individual participant to determine their needs, and then providing services that would meet those needs. If the IDT determines that private nursing services or a telephone are necessary to improve and maintain the participant's health status, those services would be covered for that participant under PACE. Therefore, these are not always or by definition excluded services, and we would eliminate paragraph (b) from the excluded services provision for that reason.

In addition to eliminating paragraphs (a) and (b), we would redesignate paragraphs (c) through (e) as (a) through (c).

We did not score this provision in the Regulatory Impact Analysis section because PACE organizations are already required to cover all PACE required services under § 460.92, and by modifying the provisions relating to excluded services we are hoping to increase compliance with existing requirements.

We summarize the comments on the proposals related to excluded services, and provide our responses to those comments, below.

Comment: All commenters that addressed this proposal expressed concern with the removal of § 460.96(b). The commenters noted that although they understand CMS' rationale for removing this provision, they believe this would impede a PACE organization's ability to deny these services when they are not necessary to maintain the participant's overall health. Specifically, commenters noted that removing this provision could be interpreted to mean that inpatient facilities, private rooms and private duty nursing services could be available without approval from the IDT. The commenters also stated that they do not believe removal of this section is necessary since the services would be provided, if determined necessary by the IDT, consistent with criteria established in § 460.92(b).

Response: We appreciate the commenters' concern and wish to explain that by removing the excluded language at § 460.96(b) we would not preclude a PACE organization from denying these services if they are determined not to be necessary. Currently, § 460.96(b) provides that private rooms, private duty nursing services and nonmedical items for personal convenience are excluded from coverage under PACE unless medically necessary or specifically authorized by the IDT as part of the participant's plan of care. As such, these services are not actually excluded from coverage under PACE, and a participant is currently able to receive these services if authorized by the IDT. We do not include other services that are excluded or denied as part of the PACE benefit package in this section and we do not believe that it is necessary to specifically list out these services and therefore are finalizing this provision as proposed. As noted in the proposed rule, we do not want to give a false impression by including services that should be considered by the IDT, as appropriate, under a section of the regulation titled "Excluded Services."

After consideration of the comments received, we are finalizing our proposed changes under § 460.96 as proposed, without modification.

3. Responsibilities of the Interdisciplinary Team

A multidisciplinary approach to care management and service delivery is a fundamental aspect of the PACE model of care (see for example, the 1999 PACE interim final rule at 64 FR 66254). The regulations at § 460.102 require in part that the IDT must comprehensively assess and meet the needs of each participant, and that the IDT members must remain alert to pertinent input about participants from team members, participants, and caregivers. While we believe many IDTs appropriately apply the multidisciplinary approach to providing care, we have learned through our monitoring efforts that some IDTs may not consider pertinent input about participants from specialists and other clinical and non-clinical staff, whether employees, or contractors (for example, home health service providers). Because these individuals have direct contact with participants, including in the participant's home, and may have a similar level of expertise as the members of the IDT listed in § 460.102(b) or expertise in another medical field, they are likely to be in the best position to provide input that may contribute to a participant's treatment plan. An IDT could not comprehensively assess a participant and provide a multidisciplinary approach to care management if it did not consider pertinent input about a participant from any individual with direct knowledge of or contact with the participant, such as caregivers, employees, or contractors of the PACE organization, including specialists. For example, if a home care aide informed the organization that a participant seems more confused than normal, the IDT might not be able to fully meet the participant's needs if it did not take this information into consideration. While the IDT is responsible for many aspects of care provided to their participants, it might not interact with their participants on a regular basis. It is important that the IDT consider input from other individuals that have more regular or direct contact with the participant population, in order to inform its ability to appropriately meet participants' needs. Therefore, we would revise § 460.102(d)(2)(ii) by adding employees, contractors, and specialists to the individuals from whom the IDT must remain alert to pertinent input. We would include specialists because there may be circumstances in which a participant is receiving care or seeking treatment options from a provider that specializes in a particular area and we believe that input

from these medical professionals is vital in order for a PACE organization to provide comprehensive care to its participants. We would add these individuals as unique sub-paragraphs under § 460.102(d)(2)(ii) in order to emphasize that these are unique groups of individuals, each of whom may provide information that is pertinent to the IDT. As part of the requirement that the IDT members remain alert to pertinent input from these individuals, we expect that the IDT members would consider all recommendations for care or services made by other team members, participants, caregivers, employees, contractors, or specialists for a participant when making treatment decisions.

We proposed a minor change to redesignate the provisions at § 460.102(d)(1) under a new (d)(1)(i), and to retain the current requirement that the IDT is responsible for the initial assessment, periodic reassessment, plan of care, and coordination of 24-hour care delivery. We would add a new § 460.102(d)(1)(ii) to require the IDT to document all recommendations for care and services and, if the service is not approved, the reasons for not approving or providing that care or service in accordance with the requirements in § 460.210(b). By requiring the IDT to document all recommendations for care or services and, if not approved or provided, the rationale supporting the IDT's decisions, we believe our proposals under § 460.102(d) would better position the PACE organization and the IDT to remain alert to pertinent information and to share that information with participants, caregivers, and appeal entities when applicable.

We believe the burden associated with this provision is related to the documentation of the recommendations in the medical record. We discuss and account for the burden of documenting these recommendations in the medical record in the regulatory impact analysis.

We summarize the comments on the proposals related to responsibilities of the IDT, and provide our responses to those comments, below.

Comment: A commenter agreed with CMS' proposed revisions at § 460.102(d)(1)(ii) which would make the IDT responsible for documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services.

However, the majority of commenters expressed concern that the requirement is not consistent with the preamble or regulatory language at proposed § 460.210(b)(4) and (5), which limits documentation to recommendations by employees and contractors of a PACE organization, including specialists, as well as the reason(s) for not approving or providing recommended services. Specifically, the commenters noted that the language as proposed at § 460.102(d)(1)(ii) could be interpreted to require the IDT to document recommendations made by the individuals other than those listed in § 460.210(b)(4).

Response: We thank the commenter who supported this provision. We do not agree, however, that the citation at § 460.102(d)(1)(ii) should be modified. We included a citation to § 460.210(b) in order to specify the IDT's responsibility for documenting all recommendations for care or services and the reasons for not approving or providing recommended care or services, if applicable, in any form encompassed under § 460.210(b). While we agree that recommendations will most often come from the individuals identified in § 460.210(b)(4), we did not propose and did not intend to limit this requirement to only those individuals. For example, redesignated § 460.210(b)(9) relates to hospital discharge summaries and, to the extent there are recommendations for care included in a summary, we would want the IDT to consider and document those recommendations. While PACE organizations contract with hospitals, it is possible that a participant would be taken to a non-contract hospital during the course of an emergency, and we would want the PACE organization to consider any recommendations for care provided by hospital staff even though the hospital was not a contract provider.

Comment: All commenters who addressed the proposals at § 460.102(d)(2)(ii), agreed with the proposal which would require the IDT to remain alert to pertinent input from any individual with knowledge of or contact with the participant. These commenters also recommended expanding the list to include the designated representative, as that individual plays a key role in the service delivery request process and appeals process.

Response: We thank the commenters for their support for this proposal and appreciate the suggestion to include the designated representative in the list of individuals that the IDT must remain alert to. We agree that designated representatives play an important role in advocating for services on behalf of the participant. We note that the change commenters suggest is consistent with our proposal; we proposed to make the individual IDT members responsible for remaining alert to pertinent input from any individual with direct knowledge of or contact with a given participant, and provided a list of examples of those individuals. The list was not all-inclusive, and we believe that designated representatives would fall within the intended class of individuals from whom IDT members must remain alert to pertinent input. Therefore, we are finalizing the regulatory text with a modification to include designated representatives among the specific list of individuals from whom the IDT must remain alert to pertinent input.

After consideration of the comments received and for the reasons outlined in our responses to comments, we are finalizing the changes to § 460.102(d)(1)(i) and § 460.102(d)(1)(ii) as proposed. We are also finalizing our proposed changes to § 460.102(d)(2)(ii) as proposed, with the exception of one modification to the regulatory text at § 460.102(d)(2)(ii)(G) to specify that the IDT must remain alert to input from designated representatives.

D. Documenting and Tracking the Provision of Services under PACE (§ 460.98)

As discussed at section VI.C. of this final rule, under sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act, PACE organizations provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required

under the PACE protocol.[79] Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. These statutory provisions ensure that a PACE participant can receive all PACE covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We have implemented these requirements in several sections of the PACE regulations. For example, we require in § 460.70 that PACE organizations must have written contracts that meet specific regulatory requirements with any outside entity furnishing administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100. We also require PACE organizations to establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year at § 460.98(a). Through oversight and monitoring, we recognized that some PACE organizations are not appropriately implementing these requirements. CMS routinely sees PACE organizations deny or restrict necessary services. PACE organizations have also documented in participants' medical records that they do not provide access to care and services 24 hours a day, regardless of participant need. CMS has also learned through monitoring of PACE organizations that some organizations are not providing all care and services through employees or contractors of the organization. Instead, these organizations purport to rely on caregivers such as family members to provide necessary care and services to participants.

We would make several modifications to § 460.98 "Service Delivery" in response to failure by certain PACE organizations to fulfill their responsibilities to provide all necessary care and services, through the use of employees or contractors, as expeditiously as the participant's

[79] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

health condition requires, and ensure access to those services 24 hours a day, every day of the year. Currently, § 460.98(a) requires that PACE organizations establish and implement a written plan to furnish the care that meets the needs of each participant in all care settings 24 hours a day, every day of the year. We are concerned that the current version of this paragraph places more emphasis on the requirement to establish a written plan than it does on the requirement that the PACE organization actually implement such a plan by furnishing services. Therefore, we would modify paragraph (a) to more clearly emphasize that PACE organizations must not only have a plan to furnish care as described in existing § 460.98(a), but must also carry it out. We proposed to change the title of § 460.98(a) from "Plan" to "Access to services" in order to emphasize the requirement is that PACE organizations must provide access to services and not just have a plan. We also proposed to revise the language of § 460.98(a) to emphasize that PACE organizations are responsible for providing care that meets the needs of each participant, across all care settings, 24 hours a day, every day of the year, as well as establishing a written plan to ensure that care is appropriately furnished. We believe the amendments would align with the statutory requirement that PACE organizations provide access to necessary care and services at all times. We would retain the requirement that PACE organizations must establish and implement a written plan to furnish care, with one modification to specify that the plan must ensure that care is appropriately furnished. Additionally, we want to emphasize that, both under the current regulation and the amendments, the PACE organization is (and would remain, if our proposed amendments are finalized) responsible for providing this care regardless of the care setting. In other words, regardless of whether the participant receives care in the home, at the PACE center, or in an inpatient facility, the PACE organization is (and would remain) responsible for furnishing care in all care settings, 24 hours a day, every day of the year.

Currently, § 460.98(b) specifies in part that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long term care to each participant, and must furnish these services in at least the PACE center, the home, and

inpatient facilities. We would make three changes to § 460.98(b) by modifying paragraph (b)(1) and adding new paragraphs (b)(4) and (5). Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, and the PACE regulations at § 460.70(a), require PACE organizations to furnish administrative and care-related services by employees or contractors of the organization. Through monitoring and oversight, we have identified instances where PACE organizations have relied on individuals other than employees or contractors to provide necessary care and services to participants. To address these concerns we added a reference to § 460.70(a) at § 460.98(b)(1) to reiterate the requirement that PACE organizations furnish all services through employees or contractors, regardless of whether the services relate to medical, health, or social services, including both acute and long term care.

We proposed to add a new paragraph at § 460.98(b)(4), to require that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs. While there is a similar requirement in § 460.104(e)(4), that services that result in a change to the care plan must be provided as expeditiously as the participant's health condition requires, we have identified through monitoring and oversight that participants routinely receive care that is determined necessary but is not formally incorporated into the care plan, and is instead handled through discipline-specific progress notes or treatment plans. For example, the primary care provider may order pain medication for a participant, but not incorporate that order into the participant's plan of care. Regardless of whether the service is in the plan of care, we believe that the PACE organization retains the responsibility of ensuring that participants receive all recommended or ordered treatment or care as expeditiously as the participant requires. We would specify at § 460.98(b)(4) that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs. We do not believe that we could implement a specific timeframe given the vast array of services that PACE organizations provide. Additionally, determining how quickly a service

must be provided would depend on more than just the physical health of the participant, and PACE organizations should consider all aspects of the participant's condition, including their social, emotional, and medical needs, when determining the provision of services. For example, if the participant has a high risk of falling, the provision of a service that mitigates that risk may be necessary within a very short window of time. However, if the necessary service is a preventative trip to the dentist for routine care, the provision of that service may not be as urgent. These decisions must be made on a case by case basis and the PACE organization will be expected to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require through monitoring efforts by CMS.

Lastly, we added a new paragraph (b)(5) to § 460.98 to require PACE organizations to document, track, and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. PACE organizations would be required to document, track and monitor necessary services in order to ensure that they are actually provided in accordance with § 460.98(b)(4). CMS' audits have revealed that in practice, certain PACE organizations do not routinely track the services provided and often lack documentation that services have been rendered. In order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care. This means that not only should a PACE organization document that a service has been ordered, but that the PACE organization should also document when and how the approved service was provided. We believe that monitoring the provision of services is vital for a PACE organization in order to ensure their participants are receiving appropriate services, and that those services are achieving the desired effect. In addition, CMS regulations at § 460.134 require that PACE organizations use objective measures to demonstrate improvement across a range of areas, such as the utilization of PACE services and the effectiveness and safety of staff-provided and

contracted services, including the promptness of service delivery, among other requirements. We believe that this proposal will ensure that PACE organizations are able to more effectively meet the minimum requirements established at § 460.134.

We summarize the comments received on the proposals related to documenting and tracking the provision of services, and provide our responses to those comments, below.

Comment: While a commenter agreed with CMS' proposals at § 460.98(a) and (b)(1), the majority of commenters requested clarification on the preamble language describing the proposals. Specifically, commenters agreed that PACE organizations are responsible for providing care that meets the needs of the participant across all care settings, 24 hours a day, every day of the year, and that neither PACE organizations nor the IDTs may require caregivers to provide necessary care or services on their behalf. However, the commenters were concerned that the preamble implied that PACE organizations cannot take into consideration family or informal caregiver support when determining which services the PACE organization must furnish in order to meet these needs. In order to clarify the regulatory requirements and CMS's position, commenters requested that CMS confirm that willing and able family members or other informal caregivers may be actively involved in a participant's care and that a PACE organization would be in compliance with the proposed regulatory requirements if the IDT considers services provided to participants by willing and able caregivers when determining which services must be provided by the PACE organization. Another commenter suggested that the regulation, as proposed at § 460.98(b)(1), would not allow any individual caregivers and informal support systems to be involved in helping meet a participant's needs without contracting with the PACE organization.

Response: As noted in the proposed rule, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require the PACE organization to provide participants with all PACE-covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We believe the existing requirements are clear.

Our proposed changes in § 460.98(a) and (b)(1) would not change the existing requirements; nor would they change how we have historically interpreted those requirements. Instead, our proposals would better align the regulatory language with the statutory requirements that require PACE organizations to provide access to necessary care and services at all times. The PACE organization is responsible for ensuring that the participant's needs are met 24 hours a day, every day of the year, consistent with the existing § 460.98(a).

We agree with commenters that a PACE organization cannot require or compel a caregiver to provide care that the IDT determines is necessary. However, we recognize that caregivers may be willing and able to provide some care to participants, such as cooking a meal or providing transportation to an appointment. None of our proposed changes would change CMS' expectations regarding the relationship between caregivers and PACE organizations. While we proposed to add a reference to § 460.70(a) at § 460.98(b)(1), we did not propose to change the requirement at § 460.70(a) or our interpretation of that requirement. Historically, CMS has interpreted the requirement at § 460.70(a) as not applicable in circumstances where family members or other informal support willingly provide care to PACE participants that could otherwise be provided by the PACE organization, without any compensation from or agreement with the PACE organization. Thus, we would not expect a PACE organization to have a contract with such caregivers unless the caregivers are providing services on behalf of the PACE organization and are receiving compensation from the PACE organization for doing so. We note that Merriam-Webster's dictionary defines willing as "done, borne, or accepted by choice or without reluctance"[80] and defines able as "having sufficient power, skill, or resources to do something"[81]. We believe these definitions are widely understood, and provide a valuable point of reference in this context.

[80] https://www.merriam-webster.com/dictionary/willing
[81] https://www.merriam-webster.com/dictionary/able

The IDT may take into consideration informal support that willing and able caregivers provide when determining what necessary services will be provided by the PACE organization directly or through contractors when developing the participant's plan of care. However, the existence of a caregiver does not absolve a PACE organization of its responsibilities to meet the needs of participants 24 hours a day, 7 days of the week. In determining how informal caregiver support affects the necessary services the PACE organization must provide directly or through contractors, PACE organizations must consider whether a caregiver is both willing and able to provide care, and whether it is safe for the participant to receive the care in question from the caregiver. This would include for example, when the PACE organization is evaluating participant and caregiver preferences for care during the initial assessments under § 460.104(a)(4)(iii) or when obtaining approval from the participant or their designated representative for a revised plan of care under § 460.104(e)(3). In particular, PACE organizations should not pressure a caregiver to provide any service that is necessary and that could otherwise be provided by the PACE organization, and should not rely on a willing caregiver to provide care if there is evidence that the caregiver cannot do so safely or in a way that meets the relevant needs of the participant. Additionally, PACE organizations may not deny a request to provide a service on the basis that a participant has a caregiver even if the caregiver has historically informally provided care that meets the participant's need for that service. We have seen through complaints and audits that PACE organizations sometimes inappropriately rely on caregivers, and in some instances attempt to require caregivers to provide care the IDT has determined is necessary for a participant, even when the caregiver is unable or unwilling to do so. For example, CMS has identified instances where PACE organizations attempted to require caregivers to provide 24-hour supervision or provide assistance with activities of daily living (ADLs) even after the caregivers indicated they could not do so, or were unwilling to do so. Through complaints and audits, we have also seen situations where a PACE organization inappropriately relied on a willing caregiver when it was not safe for the participant to receive

care from that caregiver. For example, a caregiver may be willing to provide wound care, but without the necessary skills and knowledge to provide that care, it would be unsafe for the caregiver to attend to that need because it would increase the participant's risk of infection. We note that even when a caregiver previously had elected to provide some level of assistance to a participant, their ability or willingness to provide assistance may change during the course of a participant's enrollment in PACE, rendering the caregiver unable or unwilling to continue to provide that support (e.g., the caregiver does not have a vehicle to accommodate a motorized wheelchair or the caregiver becomes ill). Similarly, a caregiver may express an interest in providing assistance, but may not be able to meet the needs of the participant. For example, the participant may need assistance with toileting, but the caregiver is physically unable to support this need. PACE organizations must ensure that when a caregiver is unwilling or unable to assist with the participant's care for any reason, that the needs of the participant are being met through employees or contractors of the PACE organization. In each of these situations, the PACE organization seems to be incorrectly or inappropriately determining that certain care and services are not needed because the PACE organization wants to rely upon a particular caregiver, even when it is clear from the circumstances that the participant needs the PACE organization to provide services because the caregiver is unwilling or unable to provide care, or because it is not safe for the participant to receive this care from the caregiver. For these reasons, we proposed to revise the regulations by adding a reference to § 460.70(a) at § 460.98(b) to ensure that PACE organizations understand their responsibilities, and we will continue monitoring PACE organizations for compliance with these requirements. We are finalizing these provisions as proposed.

Comment: A commenter recommended that CMS provide further clarification on how "coordination" and "furnish" are used and defined in the PACE regulations and to take steps to ensure that terms are used consistently throughout the PACE regulations. This commenter stated that under the proposed language at § 460.102(d)(1)(i), the IDT would be responsible for the

initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery. The commenter asserted that this has a very different meaning than the proposed requirements at § 460.98(b)(1) which states that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care, and that these services must be furnished in accordance with § 460.70(a).

Response: We agree with the commenter's observation that the proposed requirements under § 460.102(d)(1)(i) and § 460.98(b)(1) are not the same, including the fact that § 460.102(d)(1)(i) uses the term, "coordinate" while § 460.98(b)(1) uses the term "furnish." However, we did not propose that those terms would be used interchangeably. We agree that those terms have different meanings, and we believe that those terms are used appropriately within the regulation. PACE organizations are responsible for furnishing comprehensive services to PACE participants. The IDT, which consists of a subset of PACE organizations employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization.

Comment: Multiple commenters requested clarification regarding the intent of CMS's proposal under § 460.98(b)(1) to add a reference to §460.70(a) that would require services to be furnished through either an employee or contractor of the organization. Specifically, those commenters requested that CMS modify § 460.70(a) to address circumstances that might justify an exception to the requirement that PACE organizations must have a written contract with each entity that furnishes administrative or care related services not furnished directly by the PACE organization except for emergency services. As an example, commenters noted that there are times when a specialty provider may be in short supply and the PACE organization may be unsuccessful in obtaining a contract.

Response: We did not propose changes to § 460.70(a), and as such are not finalizing any changes to that section in this final rule. With regards to the commenter's question about out of

network providers, that comment relates to the topic of network adequacy for PACE organizations and we will take the commenter's feedback into consideration in future policy development for PACE.

Comment: A commenter was supportive of the provisions at § 460.98(b)(5), while the majority of commenters expressed concern with to the use of the term "track." These commenters suggested that requiring a PACE organization to track the provision of services could imply that PACE organizations would be required to establish and maintain specific logs, universes or data sets, and that such a requirement would conflict with CMS' Patients Over Paperwork initiative. These commenters stated that PACE organizations should have greater flexibility to determine how the provision of services is monitored and rather than dictating the specific manner in which PACE organizations maintain this documentation, they recommended the following regulatory text: "The PACE organization must monitor and document the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care." Additionally, these commenters requested that CMS explain that this provision would only require the PACE organization to monitor and track services furnished by the PACE organization's employees or contractors and not by caregivers.

Response: As noted in the proposed rule, in order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe that the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care (85 FR 9139). In order to ensure services are actually provided, we proposed that PACE organizations document, track and monitor services. We understand from commenters' concerns that the use of the word "track" could be interpreted to suggest that PACE organizations would be required to maintain a real time "log" of services which could potentially be burdensome to implement. As we stated in the

proposed rule, we believe that PACE organizations should document that a service has been ordered as well as when and how the approved service was provided. It was not our intention in the proposal to dictate how an organization implements this provision, and we agree with the commenter that PACE organizations should have flexibility in how they operationalize the requirement to track, monitor and document the provision of services. We expect that PACE organizations will create their own methods for tracking and monitoring services. We reiterate that the PACE organization is responsible for furnishing all services determined necessary through its employees or contractors in accordance with existing § 460.70(a) and proposed § 460.98(b)(1), and this provision would only apply to those services furnished by the PACE organization's employees or contractors.

After consideration of the comments received, we are finalizing our proposed changes to § 460.98 without modification.

E. Access to Data and Safeguarding Records under PACE (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires PACE organizations to collect data, maintain records, and submit reports, as required by CMS and the State Administering Agency (SAA). The current requirement at § 460.200(b) requires that PACE organizations must allow CMS and the SAA access to data and records, including but not limited to, participant health outcomes data, financial books and records, medical records, and personnel records. Some PACE organizations have requested clarification on whether access is limited to allowing CMS or the SAA to view requested information. CMS has long interpreted this provision to require that CMS and the SAA must be able to obtain, examine, or retrieve information as needed to administer and evaluate the program and fulfill their oversight obligations. Therefore, we proposed to codify CMS' interpretation of this requirement. Specifically, we would redesignate current § 460.200(b)(1) through (4) as § 460.200(b)(1)(i) through (iv), in order to add a new paragraph (b)(2) to state that CMS and the State administering agency (SAA) must be able to obtain, examine, or retrieve the information

described under § 460.200(b)(1). This may include CMS or the SAA reviewing information at the PACE site or remotely. It may also include CMS requiring a PACE organization to upload or electronically transmit information, or send hard copies of required information by mail.

PACE organizations are also required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. Through our monitoring of PACE organizations, CMS has discovered that PACE organizations do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community. In fact, CMS has discovered that organizations may summarize written communications and sometimes destroy or lose original written communications. When CMS has obtained copies of original communications from an outside source (such as the family or caregiver), we have noted that organizations are not accurately summarizing information or retaining the relevant information in the communication. In light of these findings, we believe that any written communication received from a participant or their informal support (for example, a family member, caregiver, designated representative, or other member of the community) that relates to the participant's care, health or safety must be safeguarded and maintained in its original form. Therefore, we proposed to modify § 460.200(d) to require PACE organizations to maintain all written communications received from a participant or other parties in their original form when the communication relates to the participant's care, health, or safety. We would expect that this would include most, if not all, communications that an organization receives on these topics. For example, the following types of communications would need to be protected under this provision: written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. We proposed corresponding

changes to § 460.210(b)(6), to require PACE organizations to maintain original written communications in the participant's medical record, as discussed at section VI.F. of this final rule.

We believe the burden associated with this provision is related to the documentation of these original communications in the medical record. We discuss and account for the burden of documenting these communications in the medical record in the regulatory impact analysis.

We solicited comments on these proposals.

We summarize the comments on the proposals related to access to data and safeguarding records, and provide our responses to those comments, below.

Comment: All of commenters who responded to this proposal requested clarification on the provision which would require access to data described in § 460.200(b)(1) both at the PACE site and remotely. Specifically, commenters requested clarity around whether or not the provision meant that the SAA and CMS would have independent remote access to PACE organizations' medical records, without the knowledge of the PACE organizations, or if it meant that CMS would require PACE organizations to make records available, either remotely or onsite, via a web-based or comparable application with the participation of PACE organization staff. Commenters stated that participation of PACE organization staff would ensure PACE organizations could maintain a record of individuals who accessed participants' medical records and would also assist CMS and SAA reviewers in locating documentation within medical records.

Response: We appreciate commenters' feedback on this proposal. As proposed under § 460.200(b)(2), CMS and the SAA must be able to obtain, examine, or retrieve the information specified at paragraph (b)(1) of that section, which may include reviewing information at the PACE site or remotely. We wish to clarify that it is not CMS's intent that CMS or the SAA would have completely unrestricted access to a PACE organization's medical records and the provision at § 460.200(b)(2) would not permit CMS or the SAA to access a PACE organization's

medical records without the PACE organization's knowledge. PACE organizations will continue to be required to grant access to medical records, which may be electronic and/or paper based, before these records are obtained, examined or retrieved by CMS or the SAA. In order to be able to obtain, examine, or access these records, CMS or the SAA may need technical assistance from PACE organization staff, but otherwise would not require staff involvement in the review process. For example, CMS or the SAA may need assistance with navigating medical record systems or locating records within medical record systems.

Comment: Commenters were split on the proposal to require original documentation to be maintained in the medical record. A commenter agreed with the proposed requirements in §§ 460.200(d)(2) and 460.210(b)(6), which would require PACE organizations to maintain all written communications received from participants or other parties, in their original form, when the communications relate to a participant's care, health or safety, including written communications from an advocacy or governmental agency. Another commenter was opposed to this provision stating that not all communication lends itself to being kept in the original form and the proposed requirement may be impracticable for mundane, routine communications such as confirming an address for a family member. This commenter recommended that CMS remove the phrase "all written communication" and instead provide a specific list of communications that must be kept in its original format. The majority of commenters requested clarification and expressed some concerns regarding the proposed requirements. This included concerns that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored. These commenters also stated that requiring direct care providers to download or otherwise transfer all such communications to the medical record would be burdensome and take them away from providing care to participants. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste

communications received via email or text into electronic medical records. The same commenters expressed concerns that the requirements were overly broad and recommended that CMS revise its proposals to both allow PACE organization staff to use their discretion when determining the types of communication that must be included in a participant's medical record and exclude communications related to processing of service requests, appeals and grievances as those communications are often kept in separate systems. Another commenter indicated that the practice of summarizing verbal conversations and documenting in the EMR should apply to written communications. This commenter also recommended that CMS clarify its expectations with regard to communications from advocacy or governmental agencies and suggested that faxes and emails requesting documents should not be placed in the medical record.

Response: We appreciate commenters' feedback and suggestions on §§ 460.200(d) and 460.210(b)(6). We address comments related to § 460.210(b)(6) in more detail at section VI.F of this final rule. PACE organizations are required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. As we stated in the proposed rule (85 FR 9134), through our monitoring and oversight efforts, CMS has discovered that PACE organizations do not always maintain and safeguard important records, and may often summarize written communications in their records and destroy or lose the original written communications. In addition, we have discovered that in some cases, PACE organizations are not always retaining or accurately summarizing all of the relevant information in those communications. Because our oversight efforts have revealed that all relevant information in written communications has not always been retained or accurately summarized by PACE organizations, we are not persuaded by commenters to allow PACE organizations to summarize written communications that relate to a participant's care, health or safety instead of maintaining the communication in its original form. In order for the IDT to remain alert to pertinent input from the participant and their caregivers,

and for PACE organizations to provide care that meets the needs of each participant in all care settings 24 hours a day, every day of the year, we believe that communications from individuals who provide information pertinent to a participant's care, health or safety, must be safeguarded and maintained in their original form. Furthermore, we are not persuaded by one commenter's suggestion that the practice of summarizing verbal communication in the medical record should also apply to written communication. We believe that summarizing verbal communication is a reasonable and necessary practice because it would be unnecessarily burdensome to require PACE organization staff to record verbal communication verbatim. In contrast, it is not necessary to summarize written communications because entire written communications can be stored in the medical record. We also believe that, in many cases, the amount of time spent summarizing the contents of written communications would exceed the amount of time necessary to enter the original documentation into the medical record, which would negate any benefits associated with summarizing the written communication.

With respect to excluding certain communications from this requirement or providing a specific list of communications that must be kept in their original format, we note that we have already limited this requirement by only requiring PACE organizations to maintain all written communications that relate to a participant's care, health, or safety. As we stated in the proposed rule (85 FR 9135), the types of communication that would be protected under this provision include, but are not limited to: written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. For example, if the participant sent the PACE organization a letter requesting long-term nursing facility placement or Adult Protective Services emailed the PACE organization to express concern about the participant's ability to live on their own, we would expect these communications to be maintained. Given the nature of the PACE program, we recognize that there is frequent communication between a PACE organization and

various individuals regarding each participant and that many of these communications would not be appropriate to maintain. For example, if a caregiver texted the PACE organization stating that they were going to be 15 minutes late in dropping off a participant at the PACE center or a participant emailed the PACE organization because they wanted to know what type of food would be served at the PACE center on a particular day, we would not expect this communication to be maintained.

After consideration of the comments received, we are finalizing § 460.200 as proposed with a minor grammatical change in the introductory paragraph of § 460.200(d), to add "a" before "PACE organization." This grammatical correction will not change the intended meaning of the regulation as proposed and described in this final rule.

F. Documentation in Medical Records under PACE (§ 460.210)

In accordance with § 460.210(a), a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, that is accurately documented and available to all staff, among other requirements. We have previously discussed the importance of maintaining a complete record for each participant. In the preamble to the 2006 PACE final rule (71 FR 71326), we stated that, because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. CMS currently specifies at § 460.210(b) the minimum required contents of a medical record. Based on audit and oversight experience, we identified additional requirements that we believe should be added under § 460.210(b) to ensure that participant medical records are fully comprehensive.

We proposed to redesignate § 460.210(b)(4) through (12) as (7) through (15), and to add three new paragraphs under § 460.210(b) to address how recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a

participant's care, health or safety should be documented in the medical record. Specifically, we proposed to add a new paragraph (b)(4) that would require the PACE organization to document all recommendations for services made by employees and contractors of the PACE organization, including by all specialists such as dentists, neurologists, cardiologists, and others, in the participant's medical record. We believe that all recommendations for services from these sources must be documented in order for the IDT to remain alert to all pertinent information, even if the IDT decides not to pursue the recommendations, for example based on a determination that the service is not necessary. Recommendations are made based on the employee or contractor's determination that a participant might benefit from a particular service given the participant's health status or condition. Even if the IDT ultimately decides that the recommended service would not be necessary to improve and maintain the participant's health status, the IDT should document that recommendation in order to remain alert to why a particular contractor or employee believed that service was necessary as required by § 460.102(d)(2)(ii).

Additionally, we proposed adding a new paragraph (b)(5) that would require the IDT to document in the medical record the reason(s) for not approving or providing a service recommended by one of these sources. When an employee, contractor, or specialist recommends a service within the scope of their authority to practice, we believe that it is necessary for the IDT to consider this information and document any decision against providing the recommended service in the medical record. For example, if a gastroenterologist recommends that a participant receive drug therapy for Hepatitis C, and after reviewing the recommendation the IDT determines that treatment is not medically necessary or is contraindicated, we would require the IDT to document in the participant's medical record the rationale for not providing the recommended drug therapy, including the clinical criteria used as the basis for that determination. This not only ensures that the IDT can review the information used to make the decision, but also that the participant has access to information about the basis of the decision not to provide a recommended service. This would also align with the requirement we finalized in

the 2019 PACE final rule (84 FR 25643) that requires the IDT to document the rationale for determining certain services are not necessary in the participant's plan of care following the initial comprehensive assessment. While the 2019 PACE final rule required the IDT to follow this process during the development of the initial care plan, we are expanding the requirement to account for situations that arise after the initial plan of care is developed. For example, a participant may be diagnosed with diabetes after the development of the initial care plan, and should the PACE organization determine that treatment is not necessary, we would expect that it document that decision and the reasons for that decision in the participant's medical record.

We also proposed to require PACE organizations to maintain certain written communications received by the PACE organization in the participant's medical record, in new paragraph § 460.210(b)(6). The PACE program presents unique challenges in terms of providing care to participants. PACE participants require a nursing facility level of care and often have complex medical needs. When a Medicare or Medicaid beneficiary is in a nursing home, they have daily interactions with staff, and their needs, including changes in condition, are noted by the staff and acted upon. PACE participants, on the other hand, largely remain in their own homes and might not be seen on a daily basis by PACE organization staff. PACE participants do, however, often have regular interactions with caregivers, family members, neighbors, and other members of their communities, as well as with social service organizations like local Area Agencies on Aging (AAA) or Adult Protective Services (APS) agencies. We believe that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health, and safety and to provide appropriate and timely care to the participant. We also believe information about a participant's care, health, or safety provided to a PACE organization by any of these sources could play a critical role in providing comprehensive care to the participant. Therefore, we proposed to add a new paragraph (b)(6) to § 460.210, to require PACE organizations to maintain, in a participant's medical record, original documentation of any written

communication relating to the care, health, or safety of a participant that the PACE organization receives from certain sources in any format (for example, emails, faxes, letters, etc.). At a minimum, PACE organizations would be required to maintain communications from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health, or safety, as well as communications from advocacy or governmental agencies like an AAA or APS. We also proposed at § 460.200(d)(2) a reference to § 460.210(b)(6) which would require that the PACE organization maintain this information in its original written form rather than summarizing the information in the participant's record. See 85 FR 9134-9135 and 9259).

We summarize the comments we received on the proposals related to the requirements for the contents of participant medical records under § 460.210(b), and provide our responses to those comments, below.

Comment: A commenter agreed with the proposals under §§ 460.210(b)(4) and (b)(5) which would require PACE organizations to document all recommendations for services made by employees or contractors of the PACE organization, including specialists, and the reason(s) for not approving or providing services recommended by these sources in the participant's medical record.

Response: We thank the commenter for their support of this provision.

Comment: Commenters were split on the proposal to require original documentation to be maintained in the medical record. A commenter agreed with the proposed requirements in §§ 460.200(d)(2) and 460.210(b)(6), which would require PACE organizations to maintain all written communications received from participants or other parties, in their original form, when the communications relate to a participant's care, health or safety, including written communications from an advocacy or governmental agency. Another commenter was opposed to this provision stating that not all communication lends itself to being kept in the original form and the proposed requirement may be impracticable for mundane, routine communications such

as confirming an address for a family member. This commenter recommended that CMS remove the phrase "all written communication" and instead provide a specific list of communications that must be kept in its original format. The majority of commenters recommended that the provisions at § 460.210(b)(6) be modified consistent with their comments on the proposal at § 460.200(d)(2). Specifically, commenters were concerned that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored. These commenters also stated that requiring direct care providers to download or otherwise transfer all such communications to the medical record would be burdensome and take them away from providing care to participants. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste communications received via email or text into electronic medical records. The same commenters expressed concerns that the requirements were overly broad and recommended that CMS revise its proposals to both allow PACE organization staff to use their discretion when determining the types of communication that must be included in a participant's medical record and exclude communications related to processing of service requests, appeals and grievances as those communications are often kept in separate systems. Another commenter indicated that the practice of summarizing verbal conversations and documenting in the EMR should apply to written communications. This commenter also recommended that CMS clarify its expectations with regard to communications from advocacy or governmental agencies and suggested that faxes and emails requesting documents should not be placed in the medical record.

Response: We appreciate commenters' feedback and suggestions on §§ 460.200(d)(2) and 460.210(b)(6). As we indicated in the discussion regarding § 460.200 at section VI.E. of this final rule, we made corresponding changes to § 460.210(b)(6) to require that the PACE organization maintain written communications in their original written form in the participant's

medical record. (85 FR 9135). We made these corresponding changes at § 460.210(b)(6) in order to establish requirements that would govern how PACE organizations must maintain written communications under § 460.200(d)(2). Currently, § 460.210(b)(7) (redesignated at 460.210(b)(10) in this rule) requires PACE organizations to document reports of contact with informal support, for example, caregivers, legal guardians, or next of kin in the participant's medical record. Since these reports of contact are already maintained in the medical record, we believe that PACE organizations should also maintain original written communication from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health or safety, as well as communications from advocacy or governmental agencies like an AAA or APS within the medical record. We believe that documenting this written communication is necessary to maintain a comprehensive medical record for each participant that is complete and accurately documented, and in order to ensure that the IDT is remaining alert to pertinent information. We do, however, agree with the commenters' recommendation that PACE organizations should be permitted to include an unaltered electronic copy, such as a scanned pdf, of the original written communication in a participant's medical record, which aligns with the intent of this proposal. As discussed in the proposed rule related to § 460.200(d)(2), we were motivated in making this proposal by a concern that PACE organizations are not accurately summarizing written communication or retaining relevant information in written communications they receive. (85 FR 9134). The original basis for the proposal at § 460.200(d)(2) also led us to establish the corresponding changes to § 460.210(b)(6) which would require PACE organizations to maintain these communications in the medical record. (85 FR 9135). We continue to believe that this proposal will ensure that PACE organizations retain relevant information received in written communications relating to the care, health and safety of a participant. We also believe that commenters' suggestion to permit PACE organizations to retain an unaltered electronic copy would be consistent with this proposal, while also reducing the burden associated with storing

the documentation in its original format. This change means that PACE organizations would be required to maintain all covered written communications described in § 460.210(b)(6)(i) and (ii), but that they can be maintained in either their original form or as an unaltered electronic copy. We believe this change to § 460.210(b)(6) will ensure that written communications are complete, accurately documented, readily accessible, and available to all staff, while allowing additional administrative flexibility for PACE organizations in operationalizing this requirement. We are not establishing specific requirements governing where affected communications must be stored within a participant's medical record. PACE organizations may operationalize these requirements in accordance with the capabilities of their medical records systems. PACE organizations may also identify which staff will be responsible for entering these communications in the medical record. Section 460.210(b)(6) does not require that covered communications be entered by direct care staff. Although direct care staff must remain alert to the pertinent information contained within these covered communications, PACE organizations may assign the responsibility for entering these covered communications to any staff, including those that does not provide direct care to participants.

After consideration of the comments received and for the reasons outlined in our responses to comments, we are finalizing § 460.210(b)(4) and (5) as proposed. We are also finalizing § 460.210(b)(6) with one modification in the regulation text, which will require PACE organizations to include original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in the participant's medical record.

G. PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to receive accurate, easily

understood information and to receive assistance in making informed health care decisions under § 460.112(b); and the participant's right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care under § 460.112(c). CMS proposed to add three new participant rights in § 460.112 to increase beneficiary protections: the right to contact 1-800-MEDICARE for information or to make a complaint; the right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines; and the right to receive necessary care across all care settings, up to and including placement in a long term care facility when the PACE organization can no longer maintain the participant safely in the community through the support of PACE services.

Section 1804(b) of the Act requires CMS to provide information on Medicare programs through 1-800-MEDICARE, as a means by which individuals may seek information and assistance for Medicare programs. This number may be utilized by Medicare beneficiaries to address coverage questions, find plan information, or make complaints related to the Medicare program. While PACE organizations are responsible for providing to all participants all services covered under Medicare and Medicaid, including prescription drugs, and other services determined necessary by the IDT to improve and maintain the participant's overall health status, PACE organizations are not required to provide this toll-free number to participants in any current communication. In the MA program, MA organizations must provide this information to beneficiaries in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) under § 422.111 as well as longstanding guidance under the Medicare Communications and Marketing Guidelines.[82] We have discovered through oversight and monitoring efforts that PACE participants and/or their caregivers are often not aware that, in addition to the internal grievance process under § 460.120, participants also have the right to contact 1-800-MEDICARE; for

[82] https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html

example, to file quality of care complaints, including filing a complaint regarding the delivery of a necessary service. For example, if the IDT approved treatment for a specific condition, but the participant never received that treatment, the participant or caregiver could call 1-800-Medicare to lodge a complaint. Given the frailty of the PACE population, we believe it is important that these participants be explicitly notified of their right to have their complaints heard and resolved by calling 1-800-MEDICARE. When a participant files a complaint with 1-800-MEDICARE, the complaint gets logged and routed to a CMS account manager or case worker in order to ensure it is appropriately responded to and resolved. To ensure PACE participants are notified about 1-800-MEDICARE, we proposed to amend § 460.112 by adding a new paragraph (b)(4) which would specify that participants have the right to contact 1-800-MEDICARE for information and assistance, including to make a complaint related to quality of care or delivery of a service. PACE organizations are required under § 460.116(c)(2) to display the PACE participant rights in a prominent location in the PACE center, and to include the participant bill of rights in the enrollment agreement under § 460.154(m). Thus, by adding (b)(4) would ensure each PACE organization makes the 1-800-MEDICARE number available to participants by posting it in an accessible location at the PACE center and including it in the enrollment agreement.

We also proposed to include a participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines at new § 460.112(c)(3). PACE organizations are responsible for ensuring participants receive all necessary care from specialists, which is coordinated through the primary care provider and IDT in accordance with § 460.102(c)(2)(ii) and (d)(1). In addition, as noted in the preamble to the 1999 PACE interim final rule that implemented the PACE program (see 64 FR 66260) and the preamble to the 2006 PACE final rule that implemented § 460.92 of the regulations (see 71 FR 71305), PACE organizations must utilize clinical practice guidelines to ensure the quality of care for PACE participants. CMS has also historically required the use of

clinical practice guidelines and professional standards in determining outcome measures applicable to the care of PACE participants as part of the PACE organizations quality improvement program (see § 460.134(b)). The 1999 PACE interim final rule also established the expectation that PACE organizations will utilize current clinical standards as a routine part of their daily operations. (64 FR 66260). Because part of the purpose of the quality improvement program is to identify areas to improve or maintain the delivery of services and patient care, CMS believes that these same guidelines and standards should be used as part of care planning and in making determinations about services as discussed in section VI.C. of this final rule. However, CMS' audits of PACE organizations have shown that some PACE participants have not received timely access to appropriate specialists as necessary to improve and maintain the participant's overall health status and in accordance with current clinical practice guidelines. Instead, the IDTs at some PACE organizations seem to be making their decisions based on factors not related to the participant's health condition. In some instances, participants have experienced negative outcomes because they have not received access to a specialist. Therefore, we proposed to redesignate paragraph (c)(3) as (c)(5) and add a new paragraph (c)(3), which expressly states each participant has the right to reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

Lastly, we added a new paragraph at § 460.112(c)(4) to address a participant's right to receive care across all care settings. A PACE organization is expected to provide for the care that is necessary for each participant and determine the appropriate setting in which to provide that care, up to and including placement in a long term care facility when a participant's condition requires it (see § 460.98(a) and (b)). However, CMS' monitoring and audit activity show that some PACE organizations are not providing long-term care services, even when their IDTs determine a participant can no longer live safely in their home and requires a higher level of care. We have learned that in some cases, affected participants disenroll from PACE in order

to receive the long-term care that is needed. One of the purposes of the PACE program is to enable frail, older adults to live in the community as long as medically and socially feasible (see § 460.4(b)(3)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care, and providing services that are accessible and adequate to meet the needs of its participants. (See § 460.98(b) and (d)(2) respectively). Lastly, enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls, or is involuntarily disenrolled. (See § 460.160(a)). A PACE organization cannot deny placement in a long-term care facility if the IDT determines the participant requires 24-hour care but the PACE organization does not have a method for providing that care in the home through either its employees or contractors. See the relevant discussion under section VI.D. of this final rule regarding providing participants access to services 24 hours a day, every day of the year, across all care settings. In order to provide more specific detail about what this fundamental program requirement entails, we added § 460.112(c)(4) which would state that a participant has the right to receive necessary care in all care settings up to and including placement in a long term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

We summarize the comments on the proposals related to PACE participant rights, and provide our responses to those comments, below.

Comment: All commenters that addressed this proposal agreed with CMS's proposal to add a participant right at § 460.112(b)(4) to inform participants of their right to contact 1-800-MEDICARE for information or assistance, including making a complaint related to the quality of care or the delivery of a service. These commenters also requested that CMS ensure that call center representatives are trained on PACE requirements and are able to handle inquiries from PACE participants.

Response: We thank the commenters for expressing support for including the 1-800-MEDICARE number in the participant rights. We are committed to ensuring that participants concerns are addressed appropriately. Call center operatives are currently educated and trained on all Medicare programs, including PACE, and should be able to fully address PACE participant inquiries. PACE participants currently have the ability to contact 1-800-MEDICARE for concerns; however, participants are not utilizing this resource frequently, potentially because of a lack of knowledge about 1-800-MEDICARE, and we expect that by requiring this telephone number to be displayed in the PACE center and included in the participant's bill of rights, participants will more frequently utilize this resource if needed.

Comment: All commenters that addressed this proposal were fully supportive of the addition of § 460.112(c)(3) and (c)(4). These commenters noted that while they agree with the addition of (c)(4), there may be situations when placement in a long-term nursing facility may not be compatible with a participant's wishes.

Response: We appreciate the commenters' support for these proposals. As noted in section VI.G. of the proposed rule, a PACE organization cannot deny placement in a long-term care facility if the IDT determines that the participant requires 24-hour care, but the PACE organization is unable to provide 24-hour care in the home through either its employees or contractors. Based on our experience overseeing PACE organizations, we have observed situations in which participants and caregivers were encouraged to disenroll from the PACE organization when long-term care placement was necessary to meet the participants needs. As required by §460.162(c), "a PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status." However, we understand that placement in a long-term care facility may not always be in line with a participant's wishes, and it is not our intent to require PACE organizations to place participants into long-term care facilities against their wishes.

After consideration of the comments received, we are finalizing this provision without modification.

H. Enforcement Action Appeal Rights under PACE (§ 460.56)

Sections 1894(e)(7) and 1934(e)(7) of the Act specify that, under regulations, the provisions at section 1857(h) of the Act, governing the procedures for termination of a contract with an MA organization, apply to the termination and sanctions of a PACE program agreement and PACE organization in the same manner as they apply to an MA organization under Medicare Advantage. The current enforcement provisions at 42 CFR part 460, subpart D, do not specify a process for appeals related to civil money penalties or intermediate sanctions. However, at § 460.54, the regulations include appeal rights for termination procedures. In the preamble to the 1999 PACE interim final rule (64 FR 66236), we discuss the requirement in the BBA of 1997 that we take into account some of the requirements established for MA as we develop regulations for PACE organizations in certain areas common to both programs, such as beneficiary protections, payment rates, and sanctions. CMS has interpreted this legal framework as granting the agency the authority to utilize the appeals processes that apply to MA organizations under § 422.756 when imposing a suspension of enrollment or payment, or imposing civil money penalties on PACE organizations. Although it has not been codified in regulation, CMS currently provides PACE organizations with these appeal rights when imposing enforcement actions under §§ 460.42, 460.46, and 460.48(b).

Therefore, in an effort to enhance transparency and ensure that PACE organizations are aware of their right to appeal an enforcement action, we added a new § 460.56 in subpart D of the PACE regulations to affirmatively state that a PACE organization may request a hearing according to the procedures at § 422.756 when CMS imposes a sanction or civil money penalty under §§ 460.42, 460.46, or 460.48(b) on PACE organizations.

For suspensions of enrollment or payment listed under §§ 460.42 and 460.48(b), CMS will follow the hearing procedures for imposing intermediate sanctions at § 422.756(b), which

includes the right to a hearing before a CMS designated hearing officer under subpart N of part 422. Under the process specified at § 422.756(b), CMS provides organizations with a notice of intent to impose sanctions and their right to a hearing before a CMS hearing officer. Organizations are given 15 days from the date of the notice to request a hearing.

For civil money penalties listed under § 460.46, CMS will follow the procedures for imposition of civil money penalties at § 422.756(e)(2)(v), which includes the right to a hearing before an Administrative Law Judge (ALJ) under subpart T of part 422. In addition, CMS must send a written notice of the agency's decision to impose a civil money penalty, the amount of the penalty, the date the penalty is due, information about the organization's right to a hearing and where to file the request for hearing.

We believe this will ensure PACE organizations understand the process CMS utilizes for imposing these enforcement actions, as well as the PACE organization's right to appeal those actions.

We did not include § 460.48(a) or (c) in the proposed rule because those provisions refer to the termination of a PACE program agreement, for which procedures are already set forth at § 460.54. However, § 460.48(b) authorizes us to withhold payment under the PACE program agreement, which is similar to the suspension of payment provided at § 460.42(b)(1). Therefore, the procedures at § 422.756 would apply, as specified at § 460.56(a).

We received no comments on our proposed new § 460.56 to address enforcement action appeal rights and therefore are finalizing this provision without modification.

I. PACE Definitions (§ 460.6)

As discussed briefly at section VI.A. of this final rule, we proposed to modify our existing definition of "services." Currently, the term "services" is defined as including items and services. We proposed a change to use the term "service" in § 460.6 to be consistent with the use of the singular in the terms defined under §460.6. The definition of the singular "service" would also apply to the plural "services." In addition, we proposed to modify our definition of

"service" to better reflect the full scope of the PACE benefit package by stating that the term "service", as used in part 460, means all services that could be required under § 460.92, including items and drugs. In the 1999 PACE interim final rule, we stated that required services included all current Medicare services, all Medicaid-covered services as specified by the state's approved Medicaid plan, and specifically included "drugs and biologicals" as a part of a list of minimum benefits PACE organizations were required to provide. (64 FR 66246 and 66301). In the 2006 PACE final rule, we removed the specific listing of all required services because we determined that it was not possible to provide a complete list of all services that must be furnished to participants if ordered by the IDT. (71 FR 71281). Instead, we adopted the language that is currently used in § 460.92 to identify the services required as a part of the PACE benefit package. Since that time, through CMS' monitoring and oversight, we have found that some PACE organizations do not realize that they are responsible for providing the full Medicare benefit, including the provision of Part D drugs. Therefore, we proposed to make changes by adding "drugs" to the definition of services for PACE purposes which is consistent with how we have historically defined the types of services that are required in PACE. We believe this change is necessary to remove potential ambiguity about the meaning of the terms "service" or "services" when used in the PACE regulations.

We received no comments on the proposed definition of "service" in § 460.6 and therefore are finalizing this provision without modification.

VII. Technical Changes

A. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

We proposed two substantive changes to § 422.220 regarding the limits on when an MA organization may or may not pay an opt-out provider. In our proposal to amend § 422.220, we sought first to align the regulatory definition of "physician" in regard to private contracts with the definition found in corresponding statute. Currently, section 1802(b)(6)(B) of the Act defines "physician," in regard to private contracts, as a term that is defined by paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act; however, § 422.220 currently defines "physician," in respect to private contracts, using only paragraph (1) of section 1861(r) of the Act – narrowing the regulatory definition to exclude physicians who are not doctors of medicine or osteopathy. To avoid confusion about what kinds of providers the opt-out and private contracting rules apply to, we proposed to extend the regulatory definition of "physician" to match the statutory definition when the term is used in regard to private contracts. We designed our proposal to achieve this by adding references to paragraphs (2), (3) and (4) of section 1861(r) of the Act to the definition of "physician" at § 422.220 to make the regulatory provision consistent with the statute.

Second, we proposed to clarify the prohibition at § 422.220 in regard to the types of items and services for which an opt-out provider may and may not receive payment from an MA organization. In the proposed rule, we discussed our interpretation of the Medicare statute that payments for supplemental benefits are outside the scope of the statutory restriction on payments to opt-out providers. Section 1802(b)(1)(B) of the Act states that an opt-out physician or practitioner must receive no reimbursement under the Medicare statute directly or on a capitated basis and "no amount for such item or service from an organization which receives reimbursement for such item or service under [Title XVIII] directly or on a capitated basis." We explained that because MA organizations only receive *reimbursement* for Part A and Part B items and services under Title XVIII of the Act, supplemental benefits are not among the items

and services for which an MA organization is prohibited from making payments to an opted-out provider. In our proposal, we recommended amending the regulations at § 422.220 to make this distinction so that paragraph (a) states the prohibition on payment while paragraphs (b) and (c) direct when an MA organization must or may nonetheless pay an opt-out provider. We use the terms "basic benefits" and "supplemental benefits" consistent with how those terms are used in §§ 422.100(c) and 422.102 and in section VI.F. of this final rule.

We received the comments noted on this proposal and our responses follow.

Comment: CMS received comments from an MA organization and a provider association in regard to our proposals. The comments CMS received were fully supportive of CMS's proposal to amend CMS's regulatory definition of "physician" at § 422.220, which pertains to private contracts between providers and Medicare Advantage enrollees, to align with the corresponding statutory definition of "physician" under section 1802(b)(6)(B) of the Act. CMS also received full support from these commenters in regard to CMS's proposal to amend § 422.220 to clarify that the restrictions on payments to opt-out providers apply only to payments for basic benefits (that is, items and services covered under Parts A and B).

Response: We thank the commenters for their remarks, and believe that in finalizing these proposals we better align our regulations with the statutes from which they originated.

We received no additional comments on this proposal. After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing these proposed changes to § 422.220 without modification.

B. Disclosure Requirements for Explanation of Benefits (§ 422.111)

In a final rule titled, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes; Final Rule" (73 FR 21504) (hereinafter referred to as the April 2011 final rule), we finalized a regulation at § 422.111(b)(12) that requires an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written

explanation of benefits, when benefits are provided under this part. Following the finalization of this regulation, CMS tested model Explanation of Benefits (EOB) templates, and, based on public comments solicited via HPMS memo and in 77 FR 70445, November 26, 2012, made final revisions to the EOB templates and issued guidance about the Part C EOBs. Subsequently, the requirement for MA organizations to furnish Part C EOBs to their enrollees applied beginning April 1, 2014.

In the February 2020 proposed rule, we sought to clarify and codify existing requirements for the Part C EOB. First, we sought to change where this requirement appears in § 422.111(b) because paragraph (b) specifies general information about the MA plan that must be disclosed to each enrollee at the time of enrollment and annually, which is not when the EOB should be sent. We also proposed to clarify that the requirement to send the Part C EOB is permanently in effect. To achieve this, we proposed to move the substance of the regulation from (b)(12) to a new paragraph (k), with a minor change to delete the phrase "CMS may require" and to add the word "must" after "MA organizations." We received no comments in regard to these two proposed changes.

We also proposed to codify the existing content requirements of the Part C EOB in new § 422.111(k)(1), (k)(2) and (k)(3). For each Part A and Part B covered item and service, mandatory supplemental benefit, and optional supplemental benefit furnished during the reporting period, we proposed that an MA organization must include a corresponding descriptor, billing code, and amount billed; total cost approved for reimbursement, share of the total cost paid by the plan; and the share of the total cost for which the enrollee is liable. We also proposed that MA organizations must include the most current year-to-date totals in the EOB: the cumulative amount billed by all providers, the cumulative total costs approved by the plan, the cumulative share of total cost paid for by the plan, the cumulative share of total cost for which the enrollee is liable, the amount an enrollee has incurred toward the MOOP limit (as applicable), and the amount an enrollee has incurred toward the deductible (as applicable). We

also proposed that MA organizations must provide clear contact information for enrollee customer service, instructions on how to report fraud, and for any EOB that includes one or more denied claims, the EOB must include a clear identification of the claim(s) denied as well as information about the denial and the enrollee's appeal rights. Our proposed regulation directed that this information about denied claims in the EOB would not replace the notice for adverse coverage decisions required by §§ 422.568 and 422.570.

We also proposed to codify the time frame choices available for MA organizations in sending the EOB. Proposed § 422.111(k)(4) would require an MA organization to choose to either send EOBs on a monthly basis or quarterly basis with per-claim notification. Consistent with our current policy, we proposed that MA organizations that send EOBs monthly must send them before the end of each month that follows the month a claim was filed and that a per-claim notice must be sent on the same cycle as a monthly EOB, which is before the end of each month that follows the month a claim was filed; MA organizations that choose to send per-claim notices must also send quarterly summary EOBs. Consistent with our current policy, we also proposed that MA organizations that choose to send EOBs on a quarterly basis must send an EOB no later than the end of each month following the quarter a claim was filed.

We summarize the comments received on our proposal and our responses follow.

Comment: A commenter asked CMS to clarify the term "filed" as it is used in paragraph (k)(4) to require the monthly EOB to be sent before the end of the month after the month in which a claim is filed and the quarterly EOB to be sent before the end of each month that follows the quarter in which a claim was filed.

Response: We clarify that we consider a claim to be filed when it has been received by an MA organization. This is consistent with our current policy.

Comment: Although CMS did not specifically discuss the existing policy that exempts MA organizations from sending EOBs to dual-eligible enrollees, one commenter asked CMS whether or not D-SNPs must send EOBs to their enrollees as a result of this rule.

Response: Currently, MA organizations are not required to send EOBs to dual-eligible enrollees, which would necessarily include any enrollee of a D-SNP, because dual-eligible enrollees generally do not pay any out-of-pocket costs. In the April 2011 final rule, we discussed the comments we solicited on this matter, and determined we would study the issue of applicability to dual-eligible enrollees (including those enrolled in D-SNPs) further under our pilot program. (76 FR 21507). At the conclusion of our pilot program, and after reviewing additional public comments solicited via a Health Plan Management System (HPMS) memo release with a 30-day comment period, as well as a November 26, 2012 Federal Register notice (77 FR 70445), the policy that exempts MA organizations from sending EOBs to dual-eligible enrollees was finalized. As we did not intend to make changes to Part C EOB policy in our proposal during this current round of rulemaking, we are finalizing this exception at § 422.111(k)(5).

Comment: A commenter, an MA organization, suggested that CMS no longer require MA plans and Part D sponsors to send Part C and Part D EOBs on a monthly basis. The MA organization stated that their enrollees experience confusion in regard to their EOBs which unnecessarily leads to complaints to their customer service department and to CMS. The MAO stated that their consumer research found that enrollees often did not read or did not know how to interpret their EOBs because the documents are lengthy and complex. They also found that their enrollees had a tendency to be interested in seeing how their cost sharing applied toward their deductible and maximum-out-of-pocket costs, and less interested in information that involves complex claims details or medical terminology. The MAO also stated that enrollees often complain about receiving EOBs on a monthly basis. The MAO recommended that CMS modify existing EOB guidance to permit MA plans and Part D sponsors to send quarterly statements to enrollees that include EOB totals related to cost sharing only, rather than the full EOB.

Response: The current Part C EOB was designed to ensure that MA enrollees have all of the information necessary to make important decisions about their health care, and its content was informed by input from MA organizations, patient advocacy groups, and other stakeholders. After publication of the April 2011 final rule, we engaged MA organizations, industry and advocacy groups, and enrollees in listening sessions to gather their feedback; using the feedback we collected, we then designed and tested models through a small pilot program with a volunteer MA organization in CY 2012. After the conclusion of this process, we sought additional public comments on the models through a Health Plan Management System (HPMS) memo release with a 30-day comment period. Based on public comment we received on the HPMS memo and a November 26, 2012 Federal Register notice, we finalized the current models for the Part C EOB. While an enrollee may not always need the entirety of the information stated in their EOB, some circumstances (for example, appeals) may arise when the enrollee needs more information than just their updated cost-sharing totals. At this time, CMS will not be changing the content requirements of the EOB; however, we acknowledge the importance of providing easily understandable information to enrollees and may consider limiting the content requirements in future rulemaking. We are finalizing the proposed option for MA organizations to use a quarterly cycle for furnishing the EOBs. We note that the regulation text does not require that the MA organization use the same cycle for every enrollee, so an MA organization may elect to provide an option for enrollees to select the monthly or quarterly cycle, provided that the applicable content and timing requirements are met. Finally, the Part D EOB notice is outside the scope of this rulemaking.

Comment: Some commenters asked that CMS reconsider the requirement to send enrollees hard copies of their EOBs. An MA organization suggested that rather that mail paper EOBs, plans should be permitted to instead send enrollees a paper disclosure notice instructing them to contact customer service to obtain a hardcopy, or go online to view an electronic copy. The same MA organization stated that plans should continue to mail hard copies of the

Integrated Denial Notice (IDN). Another commenter suggested that CMS consider changing the default requirement to electronic EOBs with paper opt-in, and stated that savings on paper, printing, and mailing could be used toward enhanced care and benefits.

Response: While CMS continues to drive innovation with respect to electronic health data access, we also recognize that a default electronic format could create disparity for enrollees who do not have the skills or equipment to obtain their claims data digitally. In order to help ensure that all enrollees are able to access their EOBs, CMS does not support a change in policy that would permit MA organizations to send EOBs electronically by default at this time. With respect to paper and electronic EOBs, CMS is not changing the requirement (finalized in section V.E of this rule) that MA organizations mail required materials in hard copy or provide them electronically following the requirements set forth in § 422.2267(d). CMS notes that in order to send an EOB to an enrollee electronically, the MA organization must obtain prior consent from the enrollee, provide instructions on how and when the enrollee can access the EOB, have a process in place through which an enrollee can request hard copies be mailed, and have a process for automatic mailing of hard copies when electronic versions are undeliverable, consistent with the requirements outlined at § 422.2267(d)(2)(ii).

Comment: An MA organization recommended that CMS provide more flexibility with regard to the frequency that an EOB can be sent to enrollees. Specifically, the MA organization suggested that CMS allow health plans to send the EOB every two weeks.

Response: Under our current policy and the regulation being finalized here at § 422.111(k), an MA organization must deliver the EOB at least on a monthly or quarterly basis, complying with the applicable content requirements. While CMS currently permits these two different frequency cycles, plans may still communicate information to their enrollees on a more frequent basis as long as the requirements of either the monthly or quarterly cycle continue to be met. At this time, CMS will not be making changes to the EOB frequency cycles or their respective requirements.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal for § 422.111(k), with one substantive modification to provide that MA organizations are not required to send the explanation of benefits to dual-eligible enrollees.

C. Special Requirements During a Disaster or Emergency (§ 422.100)

Section 422.100(m)(5)(iii) currently requires an MA organization to provide the information described in paragraphs (m)(1), (2), (3), and (4)(i) on its website, but § 422.100(m) does not have a paragraph (m)(4)(i) and paragraph (m)(4) requires a notice to CMS regarding the MA organization's ability to resume normal operations; rather, paragraph (m)(5)(i) describes the terms and conditions of payment during a public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, which is the information we intended to be posted by the MA organization. As noted in the proposed rule, the final rule that adopted § 422.100(m), titled "Medicare Program Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (80 FR 7912), was clear that the requirement at 422.100(m)(5)(iii) was to post the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable, which would enable enrollees and providers to know the payment policies for out-of-network services provided during disasters.

We proposed to amend § 422.100(m)(5)(iii) to correct the text, replacing the reference to paragraph (m)(4)(i) to paragraph (m)(5)(i). We also proposed to update the regulation text to use "website" rather than "Web site" since the non-hyphenated non-capitalized term "website" is now commonly used and more consistent with other regulations in part 422.

We received no comments on this proposal and are finalizing the proposed technical amendments to § 422.100(m)(5) for the reasons outlined in the proposed rule.

D. Effective Date for Exclusion of Coverage for Kidney Acquisitions from Basic Benefits (§ 422.100)

Section 1852(a)(1)(B)(i) of the Act defines the term "benefits under the original Medicare Fee-for-Service program option" for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide these benefits to MA enrollees. Section 17006(c)(1) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act by inserting "or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)" after "hospice care." Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans will no longer cover organ acquisitions for kidney transplants.

In the April 2019 final rule, we amended the definition of "basic benefits" at § 422.100(c)(1) to include "additional telehealth benefits," and in doing so, we also amended § 422.100(c)(1) to note the new exclusion of coverage for organ acquisitions for kidney transplants (in addition to the existing exclusion for hospice care). However, we inadvertently omitted the identification of the 2021 effective date for this change set forth in the Cures Act.

In the proposed rule, we proposed a technical correction that would add the 2021 effective date to § 422.100(c)(1) for the exclusion of original Medicare coverage for organ acquisitions for kidney transplants. Specifically, we proposed to correct the phrase "(other than hospice care or coverage for organ acquisitions for kidney transplants)" to read: "(other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants)." This provision is technical and, as stated in the proposed rule, is therefore not expected to have economic impact beyond current operating expenses.

We received no comments on this proposal and are finalizing the proposed amendments to § 422.100(c)(1) without modification for the reasons outlined in the proposed rule.

E. Add Back Cost Plan Related Sections from Previous Final Regulation (§ 422.503)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Final Rule (hereinafter referred to as the May 2014 final rule), we finalized regulations affecting the cost plan non-

renewal-related requirements (79 FR 29850 through 29851, 29959). The final regulation inadvertently identified the non-renewal section as § 422.503(b)(4)(vi)(G)(*5*)(*i*) and (*ii*) when instead the revisions should have been specified as revising § 422.503(b)(5)(i) and (ii). Although the regulatory text for the provision was published in the May 2014 final rule, it was not correctly codified in the CFR. In the February 2020 proposed rule, we proposed to designate the provision in the correct paragraph of § 422.503.

The rule we adopted in 2014 provides that an entity seeking to offer an MA organization may not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. In the February 2020 proposed rule, we proposed to codify a policy adopted in the May 2014 final rule that prohibits an organization from offering and accepting enrollment in both an MA plan and a cost plan in the same service area; that policy applied to when the MA organization and the cost plan organization were the same legal entity or corporate affiliates. The proposed rule explained the redesignation:

- In new § 422.503(b)(5)(i), we specify that an entity seeking to contract as an MA organization must not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

- In new § 422.503(b)(5)(ii), we specify that an entity seeking to offer an MA organization must not accept, or be either the parent organization owning a controlling interest of or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

We also proposed minor technical corrections to the regulation text described in the May 2014 final rule to improve the flow of the regulation text.

CMS received comments from two healthcare organizations and a trade association.

Comment: The commenters requested that the provision not be finalized, stating that it was not necessary. They commented that should CMS finalize the proposal, that it not be

applied to entities that have both a cost plan and dual eligible special needs plan (D-SNP) or EGWPs, as the likelihood of an organization moving enrollees from one of these plans to another was especially low. In addition, the commenters requested that we revise our current understanding of the service area affected by the provision to determine whether there is an overlap between a cost plan and an MA plan on a county-by-county basis.

Response: The proposal in this rule is to restore, with minor technical and grammatical changes, language from a rule published in the Federal Register on May 23, 2014, that was not included in the Code of Federal Regulations. As such, we are proposing a technical change and the comments are outside the scope of this rule. Similar comments regarding the scope of the policy and whether it should apply to D-SNPs were submitted and addressed in that earlier rulemaking. For public comments and CMS responses to policy questions on the provision, as well as additional discussion of this provision, see the May 23, 2014 final rule (79 FR 29850-29851; 29944; 29959).

After considering the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendment to § 422.503(b)(5) as proposed with minor grammatical changes.

F. Definition of "Institutionalized" (§ 422.2)

Section 1859(b)(6)(B)(i) of the Act permitted the Secretary to define the term *institutionalized* for the purposes of establishing eligibility criteria for Medicare Advantage (MA) special needs plans for individuals who are institutionalized (I-SNPs). In addition, section 1851(e)(2)(D) of the Act permitted the Secretary to define the term for purposes of eligibility for a continuous open enrollment period to enroll or change enrollment in an MA plan, except for MA MSA plans. CMS codified the current definition of *institutionalized* at § 422.2 in the January 2005 final rule (70 FR 4588) as an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for

individuals with intellectual disabilities (ICF/IID); or an inpatient psychiatric facility. This definition is used in the MA regulations (42 CFR part 422) to establish eligibility for I-SNPs and eligibility for continuous open enrollment.

We proposed to revise the definition of *institutionalized* in § 422.2 to expand the list of facilities and to add a standard to use to identify additional facilities where an institutionalized individual may reside in order to provide necessary flexibility to the regulation. Under our proposal, an institutionalized individual would be an individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare);

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid);

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act;

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act;

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act;

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act;

(7) Hospital which has an agreement under section 1883 of the Act (a swing bed hospital); and,

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) but meets both of the following: (i) furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7).

We explained in the proposed rule our concern that the current definition is too limited in scope given the array of institution and facility types in place today. We noted how our current subregulatory guidance identifies additional facilities and that the proposed changes to the

definition would align the regulatory text with existing operational practice and current guidance, clarify our policy for MA organizations, and promote the expansion of I–SNP offerings under the MA program. Our guidance (Chapter 16b of the Medicare Managed Care Manual (MMCM) and the MA Enrollment and Disenrollment Guidance[83]) taken together list the five types of institutions in the current definition and other institutions that are identified in some way in Titles XVIII or XIX of the Act in connection with the Medicare and Medicaid programs. We also explained the need for a standard that we could use to identify additional facility types, without having to go through future rulemaking, that we believed would be appropriate to use for defining when an individual is *institutionalized*. We explained how, under our proposal and using this new standard, CMS could permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I–SNPs. We explained how our proposed new definition, as a whole, could lead to additional types of I-SNPs and provide more options to Medicare beneficiaries for special needs plans targeted to the needs of individuals who are *institutionalized*.

In the proposed rule, we acknowledged that the proposed definition would not fully align with § 423.772, which defines ‘‘institutionalized individual’’ as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act. We explained that we did not believe alignment was necessary because the definition in § 423.772 serves a different purpose than the definition we proposed for § 422.2 and that differences between the two definitions had been in place since 2005, reflecting these different purposes. (85 FR 9145)

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[83] Chapter 16b of the MMCM can be found here: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf; and the MA Enrollment and Disenrollment Guidance document can be found here: https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2019_MA_Enrollment_and_Disenrollment_Guidance.pdf.

Finally, we discussed why we did not propose to change the definition of "institutionalized-equivalent" even though that term is also used to establish I-SNPs and eligibility for I-SNPs.

We received the following comments related to our proposals, and our responses follow:

Comment: A commenter stated that the proposed rule disqualifies Medicare Advantage enrollees with advanced cancer disease residing in a neoplastic disease care hospital by implementing a time requirement of 90 days, and that current subregulatory guidance in section 30.3 of Chapter 2 to the Managed Care Manual and regulations at 42 CFR § 422.62(a)(4) do not require the 90-day time requirement for an institutionalized stay.

Response: As proposed and finalized, the revised definition of the term *institutionalized* aligns with current CMS guidance and expands the definition of *institutionalized* in § 422.2 to reflect the evolution of institutions over time and the current landscape of institutional health care today. The current definition of *institutionalized* in § 422.2 includes, and has included since the definition was adopted in 2005 (70 FR 4596, 4714), the criterion that the MA eligible individual continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility. Our guidance in Chapter 2 of the Medicare Managed Care Manual, regarding enrollment and disenrollment, might not specifically address the requirement in the definition in § 422.2 that an individual reside or be expected to reside in a long term care facility of the type listed but that does not change the regulation. Because the definition includes individuals who are expected to reside in facility for a 90-day or longer continuous period, enrollment into an I-SNP may precede the 90-day point based on an appropriate assessment that the regulatory standards are met, as CMS explained in the preamble to the 2005 final rule. (70 FR 4596). The new definition of *institutionalized* maintains this criterion and identifies seven specific types of long-term care facilities rather than the original five institution types listed in the definition.

In addition, the definition in the final rule specifies that CMS may approve additional facilities that are not listed previously, but: (i) furnish similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid; and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. In implementing this final rule, CMS will establish a review process to determine whether a particular different institution type meets these standards for designation under this definition and therefore permit an MA organization to offer an I-SNP to serve beneficiaries that continuously reside in (or are expected to continuously reside for 90 days or longer in) such designated facilities, provided the plan meets the remaining qualifying criteria for I-SNPs. This new authority to identify non-listed facilities for purposes of determining if an individual is *institutionalized* is applicable for the contract and coverage year beginning January 1, 2022 and we intend to review requests from MA organizations and others to meet that timeframe for identifying facilities that meet this standard. In addition, individuals residing in institutions that qualify under this part of the definition will also be eligible for the continuous open enrollment under § 422.62(a)(4).

Comment: Another comment stated that the proposed rule would expand use of the definition by making it also applicable to the open enrollment period for *institutionalized* individuals. They note that this would have the effect of expanding a 90-day length of stay requirement to individuals for purposes of their qualification for the open enrollment period for *institutionalized* individuals (OEPI).

Response: The existing requirements establishing qualifications for the open enrollment period for *institutionalized* individuals (OEPI) are established in 42 CFR 422.62(a)(4), which provides that an individual who is eligible to elect an MA plan and who is *institutionalized*, as defined in §422.2, is not limited (except with regard to MA MSA plans) in the number of elections or changes he or she may make. The use of the definition in § 422.2 to identify individuals who are eligible for this OEPI was adopted in a revision of § 422.62(a)(4) in the

April 2018 final rule (83 FR 16616 through 16618, 16723). This final rule does not amend § 422.62(a)(4), so the revised definition of *institutionalized* at § 422.2 will apply to identify who is eligible for the OEPI. The revised definition expands the list of qualifying institutions and provides an opportunity for similar institutions to qualify. We disagree with the commenter, however, that the definition of *institutionalized*, as finalized under this rule, changes the previous requirement that an MA eligible individual must continuously reside or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility to meet the definition or to be eligible for the OEPI. Because the definition includes individuals who are expected to reside in facility for a 90 day or longer continuous period, enrollment into an I-SNP may precede the 90 day point based on an appropriate assessment.

Comment: Another commenter supported the proposed rule but had concerns that the change may hinder state Medicaid agency efforts to integrate Medicare and Medicaid programs on behalf of dual eligible beneficiaries through FIDE SNPs. First, the commenter believes that expanding the list of facilities and adding a standard to use to identify additional facilities where an institutionalized individual may reside could result in a managed care plan's ability to offer I-SNPs that do not meet the requirements to be D-SNPs to a largely dual eligible beneficiary population, and thus, the MA plan would be able operate outside of the State Medicaid Agency Contract (SMAC) requirement in section 1859 of the Act (added by the MIPPA). The commenter noted that the change in the definition of *institutionalized* creates concerns similar to the recent growth of D-SNP lookalike MA plans that CMS has sought to regulate. Second, the commenter stated that definitional change of institutionalized could potentially confuse dual eligible beneficiaries when selecting the best SNP for the beneficiary's specific needs. The commenter advised CMS and state Medicaid agencies to coordinate implementation if CMS adopted the proposed changes.

Response: We thank the commenter for their remarks, but do not share the same concerns that aligning the definition of *institutionalized* in § 422.2 with current CMS guidance

and adding a standard to recognize facilities that are not listed in the definition, but serve the same function for individuals with similar needs, would adversely impact integration of Medicare and Medicaid services for dually eligible beneficiaries. First, with regard to the specifically listed facilities in the definition, this final rule is consolidating current CMS guidance regarding I-SNP and OEPI enrollment policies and is not a significant break from them. The final rule will also provide additional flexibility to account for changes in the types of institutions that could potentially be used for I-SNPs that are not covered by the current definition of *institutionalized*. As we stated in the proposed rule, we are creating criteria that would accommodate changes in forms of institutional care within American healthcare without fundamentally changing or conflicting with other regulatory and statutory provisions surrounding I-SNPs. Under the finalized rule, the definition of *institutionalized* could include, subject to CMS approval, an additional facility that is not listed previously but (i) furnishes similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. Therefore, CMS could permit an MA organization to offer an I-SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I-SNPs. In addition, any I-SNP application containing newly authorized institutions will still need to meet the remaining review standards to gain approval

Second, we recognize that a portion of I-SNP enrollees are dually eligible for Medicare and Medicaid, and that is also true for many Medicare beneficiaries requiring a nursing level of care; however, this overlap of eligible populations is not complete. This change in the definition of *institutionalized* does not change the current requirements that establish the process for I-SNP application approval such as meeting the care management requirements for all SNPs, required by section 1859(f)(5) of the Act. Given that an MA organization would need to meet a separate set of standards, we believe there is limited incentive for an MA organization to establish an I-

SNP as opposed to a D-SNP as a means to circumvent the requirement for a contract between a state and MA organization, which is limited to D-SNPs under section 1859(f)(3)(D) of the Act and § 422.107. Finally, while we appreciate that having several plan options available for a beneficiary requires the beneficiary to think through his or her needs carefully and compare those to the specific benefits and costs of each plan, we do not believe that permitting I-SNPs to enroll individuals who continuously reside in (or are expected to continuously reside) for 90 days or longer in a facility that meets the new standard we are adopting creates unnecessary confusion or burden for beneficiaries. Having a number of plan choices will allow beneficiaries to choose among plans with potentially different plan networks, levels of out-of-pocket costs, and extra benefits like vision, hearing, and dental. We believe this ultimately increases the likelihood that beneficiaries will be able to find a satisfactory MA plan that fits their healthcare needs.

Comment: Another commenter supported the proposal, but recommended a clarification that a "facility that furnishes similar long term healthcare services that are covered under Part A or Part B or Medicaid…." includes facilities/settings where the services may be furnished by external healthcare entities that are overseen by the facility.

Response: We do not believe the proposed rule will prohibit services from being furnished by external healthcare entities as long as all other requirements are met by the I-SNP and contracted facility under the plan. Therefore, we are not making the recommended revision.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revised definition of *institutionalized* at § 422.2 as proposed. In reviewing our proposal to amend the definition of *institutionalized*, we realized that the definition of "special needs individual" in § 422.2 refers to an individual who is institutionalized but not to an individual who is institutionalized-equivalent. In the final rule published in the Federal Register on January 12, 2009 (74 FR 1495 through 1496), we first clarified that that I-SNPs can enroll individuals who are institutionalized-equivalent. In that rule, we noted that section 164 of MIPPA amended section 1859(f) of the Act, allowing institutional

SNPs to enroll a special needs individual who is living in the community but requires an institutional level of care (LOC) (that is, an "institutional-equivalent individual"). In connection with that statutory amendment, we added the definition for the term "institutionalized equivalent" to § 422.2 but failed to amend the definition of "special needs individual" to include individuals who meet the standard of being institutionalized-equivalent. In order to address this oversight, we are finalizing here a technical change in the definition of "special needs individual" to add that an individual who is institutionalized-equivalent is also a special needs individual, which is consistent with that prior final rule and our current practice.

G. Medicare Electronic Complaint Form (§§ 422.504 and 423.505)

On April 15, 2011, CMS amended §§ 422.504 and 423.505 to add a new §§ 422.504(a)(15) and 423.505(b)(22) requiring MA and Part D plans to address and resolve complaints received through CMS' complaint tracking system and to provide a direct link on their main web page to the Medicare.gov electronic complaint form. We are finalizing our proposal to modify §§ 422.504(a)(15) and 423.505(b)(22) by removing §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii) and recodifying the substance (requiring plans to display a link to the electronic complaint form on the Medicare.gov Internet Web site on the plan's main Web page) to subpart V, Communication requirements. Sections 422.111(h)(2) and 423.128(d)(2) require MA and Part D plans to maintain a website. In section VI.H. of this final rule, we are adding new §§ 422.2265 and 423.2265, which provide requirements for MA and Part D plan websites. Specifically, in §§ 422.2265(b) and 423.2265(b), we identify the required content for websites, including a link to the Medicare.gov electronic complaint form. We believe the requirement for a direct link is more appropriately addressed in CMS' website requirements rather than in §§ 422.504(a)(15) and 423.505(b)(22).

We are not making any substantive changes to §§ 422.504(a)(15) and 423.505(b)(22) other than minor changes in the text to make it clear that plans must use the CMS complaint tracking system to address and resolve complaints received by CMS against the plan. In

connection with removing §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii), we are redesignating the substance of §§ 422.504(a)(15)(i) and 423.505(b)(22)(i) as §§ 422.504(a)(15) and 423.505(b)(22).

We received no comments on this proposal and are finalizing the proposed technical amendments to §§ 422.504(a)(15) and 423.505(b)(22) without modification for the reasons outlined in the proposed rule.

H. General Requirements for Applicable Integrated Plans and Continuation of Benefits (§§ 422.629 and 422.632)

We proposed technical changes to § 422.629(k)(4)(ii) to correct four technical errors from the April 2019 final rule. Paragraph (k)(4)(ii) references Medicare coverage criteria, however Medicaid coverage criteria are also applicable during the unified appeals process described in this section. Therefore, we proposed to add the phrase "and Medicaid" following "knowledge of Medicare" in § 422.629(k)(4)(ii).

Also in paragraph (k)(4)(ii) of this section, there is an incorrect reference to the MA organization. We proposed to replace "MA organization" with the correct term, "applicable integrated plan". Also, we proposed to add the word "integrated" before "organization determination decision" to conform to the terminology used elsewhere in § 422.629(k). Lastly, we proposed to remove the comma between the words "expertise" and "in" in the regulation text to clarify that the required expertise is in the topics identified in the text.

In § 422.632(b)(1), we proposed to change the citation from § 422.633(e) to (d). Section 422.632(b)(1) reflects the requirement that the enrollee file a request for an integrated appeal in a timely manner, with a cross reference to the regulation that sets the timeframe for such appeals. Paragraph (d) of § 422.633 sets that timeframe while paragraph (e) addresses the requirements for expedited integrated reconsiderations. We therefore proposed to amend § 422.632(b)(1) to use the correct cross-reference.

We received no comments on this proposal and are finalizing the proposed technical amendments to §§ 422.629(k)(4)(ii) and 422.632(b)(1) without modification for the reasons outlined in the proposed rule.

I. Representatives in Part D Appeals (§§ 423.560, 423.566, 423.578, 423.2014, and 423.2036)

The regulations for Medicare fee-for-service (Part A and Part B) claims and entitlement appeals at part 405, subpart I, reference two types of representatives—authorized and appointed. Section 405.902 defines an authorized representative as an individual authorized under state or other applicable law to act on behalf of a beneficiary or other party involved in an appeal, and separately defines an appointed representative as an individual appointed by a party to represent the party in a Medicare claim or claim appeal. Similarly, for appeals of Medicare Part C organization determinations, § 422.561 defines "representative" as an individual appointed by an enrollee or other party, or authorized under state or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. For appeals of Medicare Part D coverage determinations, however, § 423.560 defines "appointed representative" as meaning either an individual appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee.

For consistency in the use of these terms across Medicare programs, we proposed to replace the definition of "appointed representative" in § 423.560 with a definition of "representative." We also proposed to replace references to appointed representatives in §§ 423.566(c)(2), 423.578(b)(4), 423.2014(a)(1)(ii), and 423.2036(c) and (d) with references to representatives.

We summarize the comment we received on this proposal and respond as follows.

Comment: We received one comment in support of the proposal to replace the definition of "appointed representative" in §423.560 with a definition of "representative." The commenter requested that sufficient time be built in for the implementation of this provision to allow affected enrollee communications documents to be modified to reflect this change.

Response: We appreciate the commenter's support for this proposal. Given that we are enhancing consistency in the use of the term "representative" across the Medicare program and not substantively altering the concept of who may be a representative in the grievance and appeals processes, we believe the effective date of this rule affords plans ample opportunity to make any necessary changes to enrollee communications.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, without modification, the proposed amendments to §§ 423.560, 423.566, 423.578, 423.2014, and 423.2036 to clarify and streamline references to "representatives" in the Part D appeal regulations.

J. Copayments and Coinsurance in Amount in Controversy Calculations (§§ 422.600 and 423.2006)

We proposed amendments to §§ 422.600 and 423.2006 to clarify how the amount in controversy (AIC) is calculated for appeals for MA plans, section 1876 cost plans, section 1833 health care prepayment plans and Part D plans. The regulations applicable to cost plans and healthcare prepayment plans, §§ 417.600 and 417.840 respectively, require those plans to also use the MA appeal regulations.[84]

We explained in the proposed rule the statutory background for using the same rules for calculating the AIC as used for the Medicare FFS program for MA appeals. The regulations at part 405, subpart I, specifically § 405.1006(d), provide the methodology for calculating the amount in controversy (AIC) in Medicare fee-for-service (Part A and Part B) claims and entitlement appeals. In general, and subject to the exceptions listed in §§ 405.1006(d)(2) through (6), § 405.1006(d)(1) provides that the AIC is computed as the amount that the provider or supplier bills ("the actual amount charged the individual") for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or

[84] We cited § 405.840 in the proposed rule but provide the correct citations here.

services, and further reduced by "any deductible and/or coinsurance amounts that may be collected for the items or services."

For Medicare Part C appeals under part 422, subpart M, § 422.600(b) provides that the AIC is computed in accordance with the part 405 rules (concerning appeals of initial determinations under original (fee-for-service) Medicare). However, we stated in the proposed rule that while original Medicare uses deductibles and coinsurance (where the beneficiary pays a percentage of the cost for an item or service) as forms of cost sharing, MA plans may also use copayments (where the enrollee pays a flat fee for an item or service) as a form of cost sharing. We stated in the proposed rule that because § 405.1006(d)(1) provides that the AIC excludes "any deductibles and/or coinsurance amounts that may be collected for the items or services," questions have arisen regarding whether it is also appropriate to exclude any copayment amounts that may be collected for the items or services when applying the part 405 rules to appeals of Part C organization determinations made under part 422, subpart M. To resolve ambiguity on the proper calculation of the AIC and to help ensure that the AIC in Part C appeals is reflective of the actual amount at issue for the enrollee, we proposed to revise § 422.600(b) to clarify that the AIC, which can include any combination of Part A and Part B services, is computed in accordance with part 405, and that any references to coinsurance in the part 405 regulations, for purposes of computing the AIC under § 422.600, should be read to include both coinsurance and copayment amounts.

We also proposed a revision to the regulations for appeals of Part D plan sponsor coverage determinations and at-risk determinations made under part 423, subpart M. The AIC for these appeals is addressed in § 423.2006, which does not reference cost-sharing amounts. To clarify the AIC calculation for Part D appeals and help ensure that the AIC in Part D appeals is reflective of the actual amount at issue for the enrollee, we proposed to redesignate paragraphs § 423.2006(c)(1) and (2) to (2) and (3), and to amend (c)(1) to provide general AIC calculation provisions for Part D appeals, specifying that the AIC calculation would be reduced by any cost-

sharing amounts, including deductible, coinsurance, or copayment amounts, that may be collected from the enrollee for the Part D drug(s).

We received no comments on these proposals and are finalizing amendments to §§ 422.600 and 423.2006 without modification to clarify application of the AIC rules to Part C and Part D appeals, for the reasons outlined in the proposed rule.

K. Stipulated Decisions in Part C (§ 422.562)

The regulations for Medicare fee-for-service (FFS) (Part A and Part B) claims and entitlement appeals at part 405, subpart I provide for stipulated decisions at § 405.1038(c). This provision permits Office of Medicare Hearings and Appeals (OMHA) adjudicators to issue abbreviated, stipulated decisions if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made.[85] In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the written or oral statement and without making findings of fact, conclusions of law, or further explaining the reasons for the decision. The MA appeal regulations at § 422.562(d) provide that the FFS appeals procedures in part 405, subpart I apply to appeals of Part C organization determinations to the extent they are appropriate and identifies specific part 405 regulations that are not appropriate to apply to MA appeals. We explained in the proposed rule that because MA organizations are not generally included within the definition of "contractors" in § 405.902, it was not readily apparent that the rules for stipulated decisions at § 405.1038(c) apply to MA appeals. For consistency with the Part D regulations (which allow stipulations to be made by Part D plan sponsors under § 423.2038(c)), and to afford OMHA adjudicators the same flexibilities in Part C cases where the MA organization that issued the organization determination and plan reconsideration no longer disputes that an item or service should be

[85] For appeals in which the amount of payment is an issue before the ALJ or attorney adjudicator, § 405.1038(c) further provides that the written or oral statement must agree to the amount of payment the parties believe should be made.

covered or that payment should be made, we proposed to revise § 422.562 by adding new paragraph (d)(3) to clarify that, for the sole purpose of applying the regulations at § 405.1038(c) to Part C appeals under part 422, subpart M, an MA organization is included in the § 405.902 definition of "contractors" as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators. As we stated in the proposed rule, we believe this revision will permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, which would ultimately benefit MA enrollees because these decisions could potentially be issued, and effectuated by the MA organization, sooner.

We received no comments on this proposal and therefore are finalizing the proposed changes to § 422.562 without modification for the reasons provided in the proposed rule.

L. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)

Section 1860D-4(c)(5)(C)(ii) of the Act contains exemptions from DMPs for certain beneficiaries, and provides the Secretary with the authority to elect to treat other beneficiaries as an exempted individual. As currently codified at § 423.100, exempted beneficiaries include those receiving hospice or end-of-life care, residents of a long-term care facility, or those being treated for active cancer-related pain.

Consistent with the statutory authority and current clinical literature detailed in the preamble of the proposed rule, CMS proposed to add beneficiaries with SCD to the categories of exempted beneficiaries in § 423.100.

Comment: CMS received a number of comments on this proposal, which were unanimously supportive of adding beneficiaries with SCD to the list of individuals exempted from DMPs.

Response: CMS thanks the commenters for their support.

Comment: Several commenters suggested that individuals with other disease states also should be exempt from DMPs, including: chronic pain in cancer survivors, any chronic pain, complex regional pain syndrome, fibromyalgia, rare chronic pain diseases, Ehlers Danlos

syndrome, degenerative disc disease, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, common variable immunodeficiency, and non-pain syndromes for which opioids are utilized, such as dyskinesias and autoimmune conditions affecting the excretory system.

Response: CMS appreciates these suggestions but disagrees that additional exemptions from DMPs are warranted at this time. In the April 2018 final rule establishing DMPs (83 FR 16454), CMS stated that if exemptions are crafted too broadly or are too numerous, they would risk undermining the purpose of DMPs, which serve as a patient safety tool for beneficiaries who use opioids. CMS believes it is appropriate to narrowly tailor exemptions, distinguish between different clinical scenarios, and account for differences in coordinating care in distinct patient populations. The clinical presentation of SCD is such that individuals with this condition regularly require access to opioid pain medications when experiencing acute crises in addition to treatment for chronic pain and are more likely to have additional prescribers due to frequent visits to emergency rooms.[86] These factors lead to beneficiaries with SCD being identified as PARBs by OMS criteria while case management, care coordination, and DMP coverage limitations are less practicable for them. Thus, while CMS appreciates commenters' feedback on additional disease states to be considered for exemption from DMPs, at this time CMS does not have sufficient data to demonstrate that the clinical presentation and factors affecting care coordination for the other disease states mentioned in comments make DMP activities of similarly limited value. However, CMS will continue to evaluate OMS response data, other available data sources, and medical literature for consideration in future policy development. In addition, CMS monitors DMPs to ensure they are functioning in the positive ways CMS anticipates will support appropriate pain management.

[86] James, CV and Wilson-Frederick, SM. The Invisible Crisis: Understanding Pain Management in Medicare Beneficiaries with Sickle Cell Disease. CMS Office of Minority Health Data Highlight, No. 12. Baltimore, MD. 2018. Available from: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CMS-OMH-September2018-Sickle-Cell-Data-Highlight.pdf

Comment: A commenter stated that disease-specific exemptions are discriminatory against beneficiaries with other diseases that involve pain and may require opioid therapy, such as inherited autoimmune disorders like ankylosing spondylitis and rheumatoid arthritis and generalized osteoarthritis.

Response: CMS disagrees that the sickle cell disease exemption we proposed is discriminatory. As background, section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who (I) receives hospice care, (II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or (III) the Secretary elects to treat as an exempted individual. While the first two exemptions are required under CARA, CMS previously exercised the authority in section 1860D–4(c)(5)(C)(ii)(III) of the Act to establish the exemption for a beneficiary who is being treated for active cancer-related pain and is exercising that authority in this rule to exempt beneficiaries with SCD. These discretionary exemptions are not discriminatory toward beneficiaries with other diseases that may require opioid therapy because inclusion in a DMP is not a punitive step. Inclusion means that a beneficiary's opioid use will be reviewed during case management for medical necessity and safety, and DMPs do not dictate the amount or length of opioid use for a beneficiary that is deemed medically necessary. Additionally, CMS adopts discretionary exemptions as part of our ongoing efforts to minimize identification of "false positives," that is, beneficiaries are exempted who may meet OMS criteria but are unlikely to need case management for their safety and medical necessity review.

Comment: A few commenters requested additional flexibilities to include SCD patients in DMPs if case management suggested intervention would benefit them or if they were previously identified as an ARB and a coverage limitation was applied.

Response: Plan sponsors are not permitted to include exempted individuals in their DMPs. Based on the statutory language at section 1860D-4(c)(5)(C) of the Act, current CMS

guidance[87] states that: 1) exempted beneficiaries cannot be placed in a Part D sponsor's DMP, 2) a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report, and 3) a beneficiary's identification as an ARB terminates as soon as a sponsor discovers that the beneficiary is exempted. Other than adding individuals with SCD to the existing exemptions starting January 1, 2022, this final rule does not change existing policy with respect to exempted individuals.

Comment: A few commenters requested that CMS update OMS technical elements (for example, response codes) consistent with the final provision.

Response: CMS appreciates this comment and intends to update OMS response forms and technical guidance accordingly.

After consideration of the comments received and for the reasons provided in the proposed rule and preceding responses to comments, CMS is finalizing the exemption for beneficiaries with SCD as proposed with one modification to clarify that this definition is applicable starting in plan year 2022 instead of plan year 2021.

M. Drug Management Programs (DMPs): Additional Requirements (§§ 423.100 and 423.153)

In order to improve the clarity of the DMP regulations, CMS proposed a number of technical wording and reference changes. CMS received no comments on these proposed revisions and are finalizing them without modification for the reasons given in the proposed rule. In response to a comment received on the provision to include beneficiaries with a history of opioid-related overdose in DMPs in section III.B., CMS is making an additional technical change to add "who is not an exempted beneficiary" to the PARB definition at § 423.100. This change makes the definitions for PARB and ARB consistent and codifies existing guidance that once a PARB is determined to be an exempt beneficiary, they are no longer to be included in DMPs.

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[87] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf

CMS also noticed a grammatical error at § 423.153(f)(15)(ii)(D). In order to improve the clarity of the statement at this citation, CMS is changing the two occurrences of "no later than 7 days of the date" to "no later than 7 days from the date" in this statement.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a "collection of information," as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our February 2020 proposed rule solicited public comment on our proposed information collection requirements, burden, and assumptions. Summaries of the public comments on the proposed information collection requirements, burden, and assumptions for the policies being implemented in this final rule are included in this section with our responses under: (1) ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111), (2) ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153), (3) ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128), (3) ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514), and (4) ICRs Regarding PACE.

We did not receive PRA-related comments pertaining to: (1) ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101), (2) ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153), (3) ICRs

Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153), (4) ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111), (5) ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2), (6) ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128), and (7) ICRs Regarding Stipulated Decisions in Part C (§ 422.562).

The following provisions of the February 2020 proposed rule were finalized in our June 2020 final rule (85 FR 33796) and are thereby excluded from this final rule: (1) ICRs Regarding Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102), (2) ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514), (3) ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110), (4) ICRs Regarding Medical Loss Ratio (MLR) (§ 422.2440), and (5) ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38).

A. Wage Data

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm), which, at the time of publication of this rule, provides May 2019 wages. In this regard, Table H1 presents the mean hourly wage, the

cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE H1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Compliance Officer	13-1041	35.03	35.03	70.06
Computer Programmers	15-1251	44.53	44.53	89.06
Computer Systems Analysts	15-1211	46.23	46.23	92.46
Dietician	29-1031	29.97	29.97	59.94
General Operations Manager	11-1021	59.15	59.15	118.30
Health Technician, All Other	29-9098	28.17	28.17	56.34
Healthcare Social Workers	21-1022	28.51	28.51	57.02
Management Analyst	13-1111	45.94	45.94	91.88
Occupational Therapist	29-1122	41.45	41.45	82.90
Office and Administrative Support	43-9199	18.41	18.41	36.82
Medical and Health Services Managers (PACE Center Manager)	11-9111	55.37	55.37	110.74
Passenger Vehicle Driver	53-3058	15.97	15.97	31.94
Personal Care Aides	31-1120	12.71	12.71	25.42
Pharmacist	29-1051	60.34	60.34	120.68
Physical Therapist	29-1123	43.35	43.35	86.70
Physician	29-1216	96.85	96.85	193.70
Recreational Therapist	29-1125	24.58	24.58	49.16
Registered Nurse	29-1141	37.24	37.24	74.48

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2018 wage estimates, this final rule uses BLS's more recent May 2019 wage estimates. Changes to the wage estimates represent shifts in average wages of occupations between 2018 and 2019 and are presented in Table H2. The table also reflects occupation titles used in both the

proposed rule and this final rule with corresponding changes in wages and changes in occupation codes.

TABLE H2: COMPARISON OF PROPOSED AND FINAL RULE WAGE DATA

Occupation Title	CMS-4190-P: Occupation Code (BLS: May 2018)	CMS-4190-F2 Occupation Code (BLS: May 2019)	CMS-4190-P: (BLS: May 2018($/hr))	CMS-4190-F2: (BLS: May 2019 ($/hr))	Difference ($/hr)
Compliance Officer	13-1041	No change	69.72	70.06	+0.34
Computer Programmers	15-1131	15-1251	86.14	89.06	+2.92
Computer Systems Analysts	15-1121	15-1211	90.02	92.46	+2.44
Dietician	29-1031	No change	58.86	59.94	+1.08
General Operations Manager	11-1021	No change	119.12	118.30	-0.82
Healthcare Social Workers	21-1022	No change	56.22	57.02	+0.80
Management Analyst	13-1111	No change	90.76	91.88	+1.12
Occupational Therapist	29-1122	No change	82.08	82.90	+0.82
Office and Administrative Support	43-9199	No change	36.04	36.82	+0.78
Medical and Health Services Managers (PACE Center Manager)	11-9111	No change	109.36	110.74	+1.38
Personal Care Aides	31-1011	31-1120	24.36	25.42	+1.06
Pharmacist	29-1051	No change	118.90	120.68	+1.78
Physical Therapist	29-1123	No change	85.46	86.70	+1.24
Physician	29-1069	29-1216	196.04	193.70	-2.34
Recreational Therapist	29-1125	No change	48.68	49.16	+0.48
Registered Nurse	29-1141	No change	72.60	74.48	+1.88

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VII) of this final rule.

1. ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

The following changes will be submitted to OMB for approval under control number 0938-1296 (CMS-10565). Subject to renewal, the control number is currently set to expire on June 30, 2022. It was last approved on June 30, 2019 and remains active.

This rule amends § 422.101(f) to implement the new requirements legislated by the BBA of 2018 to section 1859(f) of the Act for C-SNPs and to extend them to all SNP types.

Specifically, we are adding the following new regulations to account for new requirements governing SNP enrollee care management and SNP MOC submissions. The new regulations impacting MA SNP MOCs consist of the following:

• We are amending the end of § 422.101(f)(1)(i) by adding the following language: "…and ensure that results from the initial and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section." To comply with this provision, MA SNPs will have to provide the necessary guidance to SNP plan staff and develop related internal processes for employees of the SNP that are responsible for incorporating this requirement into their MOC.

• New § 422.101(f)(3)(ii)(A) through (C) will implement the requirement that: as part of the evaluation and approval of the SNP MOC, NCQA must evaluate whether goals were fulfilled from the previous MOC; plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals; plans submitting an initial MOC must provide relevant information pertaining to the MOC's goals for review and approval; and if the SNP MOC did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. Under this change, each plan's MOC must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals. Note, all SNPs are currently required to identify and clearly define measurable goals and health outcomes as part of their MOC under MOC 4, Element B: Measurable Goals and Health Outcomes for the MOC.

• Lastly, new § 422.101(f)(3)(iii) will implement the requirements that each SNP MOC submitted to CMS will be evaluated by NCQA based on a minimum benchmark (of 50 percent) for each of the existing four elements.

At the time SNP applications are due, MA organizations wishing to offer a new SNP will submit a MOC with their SNP application in the Application module in HPMS for NCQA

review and approval. MA organizations wishing to renew their current SNP will submit a MOC in the MOC module in HPMS for NCQA review and approval. Based on their MOC scores, I-SNPs and D-SNPs receive an approval for a period of 1, 2, or 3 years. C-SNPs must renew their MOCs annually per section 1859(b)(6)(B)(iii) of the Act. For calendar year 2020, CMS received 273 SNP MOCs during the annual submission process and received 11 off-cycle submissions during the following time period. We believe these figures are representative of future SNP MOC submission totals going forward.

The burden related to these new requirements for SNP MOCs reflect the time and effort needed to adhere to the new requirements under the amendments to § 422.101(f), and as listed in the bullets in this section, and collect the information as previously described, as well as all other MOC data, and report this information to CMS. To derive average costs, we selected the position of registered nurse because the SNP nurse usually develops and submits the MOC to CMS and typically interacts with the health plan quality registered nurse in matters related to the MOC after it is submitted to CMS.

As is current practice, the MA organization/SNP will click on the Application or MOC module in HPMS and download the SNP MOC Matrix document. The SNP will complete the document, and then upload its MOC matrix document with the MOC narrative. The SNP MOC Matrix upload document outlines the CMS SNP MOC standards and elements that must be addressed in the MOC narrative. The document also serves as a table of contents for the MOC narrative.

Training to use the MOC module will be minimal at 3 hours annually, and training materials and non-mandatory webinar sessions are provided by CMS at no cost to the SNPs except for the time (and cost) to participate. While the training is not mandatory, SNP personnel (we believe this is a SNP compliance officer at $70.06/hr) normally attend the full 3-hour session. In aggregate, we estimate an ongoing annual burden of 819 hours (273 SNPs * 3 hr) at a cost of $57,379 (819 hr * $70.06/hr).

Using HPMS contract year 2020 submission data, for annual submissions under 42 CFR § 422.101(f)(3) we estimate that each year 273 SNPs will submit MOCs. Note, this calculation is based on estimates that include annual MOC submissions for C-SNPs and semi-annual submissions for I-SNPs and D-SNPs. I-SNPs and D-SNPs submitting a MOC can receive MOC approval for one, two, or three year terms. For each SNP, we assume an additional 6 hours at $74.48/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 1,638 hours (273 SNPs x 6 hr) at a cost of $121,998 (1,638 hr x $74.48/hr).

For plans seeking to revise their MOC based on qualifying events during the off-cycle season, we estimate that approximately 11 SNPs (D-SNPs/I-SNPs) will submit off-cycle MOC changes based on historical submission rates. For each SNP submitting off-cycle MOC changes, we assume an additional 4 hours at $74.48/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 44 hours (11 SNPs x 4 hr) at a cost of $3,277 (44 hr x $74.48/hr).

Since § 422.101(f)(3)(iii) sets a minimum benchmark for each MOC element, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at data for contract year 2020, our element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. For contract year 2020, 7 plans required submitting their MOCs for revision based on the current scoring system and an additional 7 plans decided to withdraw their MOCs before the revision process for a total of 14 MOCs. The 14 SNPs must resubmit, taking 3 hours, or half the full 6-hour estimate. In aggregate, we estimate an added ongoing annual burden of 42 hours (14 SNPs * 3 hr) at a cost of $3,128 (42 hr * $74.48/hr).

For the aforementioned MOC requirements under the amended 42 CFR § 422.101(f)(3), we estimate an added annual burden of 2,543 hours (819 hr for training to use the MOC module + 1,638 hr for MOC submissions + 44 hr for MOC revisions + 42 hr for MOC resubmissions) at a cost of $185,782 ($57,379 + $121,998 + $3,277 + $3,128, respectively).

Separate from the MOC process, newly added § 422.101(f)(1)(iv) will implement a new requirement that plans provide face-to-face encounters with consenting individuals enrolled in the plan not less frequently than on an annual basis. The new regulation requires an annual face-to-face visit, that is, in-person or by visual, real-time, interactive telehealth technology, to occur starting within the first 12 months of enrollment within the plan. CMS will consider a visit to or by employed and/or contracted staff that perform clinical functions, such as direct enrollee care, as a qualifying encounter. Such activities may include, but are not limited to, annual wellness visits and/or physicals, HRA completion, meeting with the interdisciplinary team (IDT), care plan review, health-related education, and care coordination activities. It is also the expectation that any concerns related to physical, mental/behavioral health, and overall health status, including functional status, are addressed and any appropriate referrals, follow-up, and care coordination activities are provided or scheduled as necessary.

We believe that most, if not all, SNP enrollees will have a qualifying face-to-face encounter under § 422.101(f)(1)(iv) through an initial or annual HRA, a qualifying encounter with an IDT member, or an annual wellness visit. We estimate that approximately 734 SNPs that have at least 11 members will need to track face-to-face encounters for their enrollees annually. For each SNP tracking face-to-face encounters, we assume 4 hours of work by SNP personnel, typically a registered nurse. In aggregate, we estimate 2,936 hours (734 SNPs x 4 hr) at a cost of $ 218,673 (2,936 hr x $74.48/hr).

Section 422.101(f)(1)(iii) will also require that MA organizations offering a SNP must provide each enrollee with an IDT in the management of care that includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan. Plans must develop and implement this requirement into their MOC components to assure an effective management structure. We believe this requirement is consistent with currently approved information tracking practices for

all existing SNPs, and thus, does not impose any new or revised requirements and/or burden beyond what is currently approved by OMB under the aforementioned control number.

The remaining changes under § 422.101(f)(2) and (3), will codify current guidance governing SNP MOC submission practices, which is captured under our active information collection request.

We received no comments on our proposed burden estimates. Consequently, we are finalizing them without modification.

2. ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)

The following changes will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

As discussed in section III.A. of this final rule, we are codifying the requirement under section 2004 of the SUPPORT Act that Part D plan sponsors establish DMPs by 2022 at § 423.153(a).

For context, in general, the required elements of a DMP are codified at § 423.153(f). The provisions require Part D sponsors to conduct case management of PARBs identified by OMS through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines.[88] After case management is completed, if a plan sponsor intends to limit a beneficiary's access to coverage of opioids and benzodiazepines, the sponsor must provide an initial written notice to the beneficiary. After the beneficiary has a 30-day time period to respond, the plan sponsor sends a second notice to the beneficiary, if the sponsor determines the beneficiary is an at-risk beneficiary (ARB), that the sponsor is implementing a coverage limitation on opioids and/or benzodiazepines, or an alternative second notice if the plan sponsor

[88] CMS currently designates both opioids and benzodiazepines as "Frequently Abused Drugs" for purposes of DMPs. See "Part D Drug Management Program Policy Guidance", November 20, 2018, p. 6; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf

determines that the beneficiary is not an ARB. Thus, every beneficiary who receives an initial notice receives a second or alternate second notice.

In 2019, a CMS internal analysis found that a majority of Part D contracts (669 of 779, or 85.9 percent) voluntarily included a DMP. Our requirement that sponsors adopt DMPs would only affect the remaining minority of sponsors currently not offering such programs. There are 111 contracts (plan sponsors) run by 79 parent organizations that would be involved. Furthermore, we estimate that only 158 additional PARBs will be identified by these 111 contracts due to meeting the minimum OMS criteria. We estimate burden at the parent organization level because we believe that is a closer reflection of the number of systems that will need to be updated versus the contract level.

The estimated reporting burden to these sponsors has four aspects. Under § 423.153(f), sponsors must: (1) design a DMP; (2) conduct case management, which includes sending written information about PARBs to prescribers; (3) program and issue written notices to PARBs and ARBs; and (4) report data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

For one-time initial development, we estimate it would take each parent organization without a DMP 80 hours for a team of four clinical and non-clinical staff to design its DMP. Thus the burden for one parent organization is 320 hours (80 hr x 4 staff). Therefore, the aggregate burden for the 79 remaining parent organizations to develop DMPs consistent with the requirements of §423.153(f) is 25,280 hours (79 parent organizations x 320 hr).

With regard to costs, we estimate that development, as just indicated, will require a development team consisting of four staff, two pharmacists (working at $120.68/hr) and two general operation managers (working at $118.30/hr) per organization. Thus, the average hourly wage for the organization's development team is $119.49/hr ($477.96/hr / 4 staff). The rates for the development team are summarized in Table H3. Consequently, the aggregate cost to develop

the DMPs is $3,020,707 ($119.49/hr * 25,280 hr) or $38,237 per parent organization ($3,020,707 / 79 organizations).

TABLE H3: LABOR RATES FOR THE DEVELOPMENT TEAM

Occupation	Hourly Wage ($/hr)	Number of Staff	Total Wages ($/hr)
General operations manager	118.30	2	236.60
Pharmacist	120.68	2	241.36
Total (for hourly wage and total wages)	119.49*	4	477.96

*Note: 119.49 is the average wage per hour (477.96/4) and equals total wages for four staff (477.96) divided by total staff (4). The 119.49 is a weighted average representing the hourly wage of the team; that is a team of four working on average at $119.49 / hr. incur a total cost of $477.96. The reason an average is taken is because not all four members are working all the time. This number is important since it enters the summary table and is the only number that when multiplied by number of hours (4 staff * 1 hr) will give the correct total wage. Since this number is not a total, the "Totals" row header has been clarified to indicate that totals only apply "hourly wage" and "total wages". This is a standard practice.

The 79 Part D parent organizations affected by this requirement also will have to upload beneficiary notices into their internal claims systems before they can issue them. We estimate that it will take each organization, on average, 5 hours at $89.06/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimated a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $35,179 (395 hr * $89.06/hr).

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 parent organizations that did not voluntarily establish a DMP are generally smaller plans that in some cases offered alternative means of managing comprehensive beneficiary care, such as through PACE. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on internal analysis of the first 3 quarters (January-March, April-June, and July-September of 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate of 0.7 percent of beneficiaries extrapolated over the entire year, CMS can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

Once required DMP policies are developed and operational, sponsors would have to case-manage their PARBs (as outlined in § 423.153(f)(2)). The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. The burden for sending this information, which may be accomplished by any of several means (such as mail or fax), is already included in the case management burden estimates provided earlier in this section and does not need to be separately accounted for.

The case management team would consist of a pharmacist (such as initial review of medication profiles, utilization, etc.) working 2 hours at $120.68/hr; one health technician working 2 hours at $56.34/hr; and one physician working 1 hour at $193.70/hr to work directly with providers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $547.74 per PARB case managed ([2 hr x $120.68/hr] + [2 hr * $56.34/hr] + [1 hr * $193.70/hr]). Therefore, the case management team's wage is $109.55/hr ($547.74 / 5 hr). This is summarized in Table H4. In aggregate, we estimate an annual burden of 790 hours (5 hr x 158 beneficiaries at a cost of $86,545 per year (790 hr x $109.55/hr).

TABLE H4: HOURLY WAGE OF CASE MANAGEMENT TEAM

Occupation	Time (hours)	Wages ($/hr)	Labor cost ($)
Health Technician	2	56.34	112.68
Pharmacist	2	120.68	241.36
Physician	1	193.70	193.70
Totals (For hours and labor cost)	5	109.55*	547.74

*Note: 109.55 is the average wage per hour (547.74/5) and equals total wages for five staff (547.74) divided by total staff (5). The 109.55 is a weighted average representing the hourly wage of the team; that is a team of five working on average at $109.55 / hr. incur a total cost of $547.74. The reason a weighted average is being used is because not all team members are working at each instant. This number is important since it enters the summary table and is the only number that when multiplied by number of hours (5 staff * 1 hr) will give the correct total wage. Since this number is not a total, the "Totals" row header has been clarified to indicate that totals only apply "hours" and "labor cost". This is a standard practice.

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimated that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). At most, 8 sponsors would be responsible for sending the notices to these 8 beneficiaries. CMS estimates it

will take 10 minutes (0.1667 hr) at $56.34/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden for sending notices to beneficiaries of 1.3336 hours (8 beneficiaries x 0.1667 hr) at a cost of $75 (1.3336 hr x $56.34/hr).

Under § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy will be required to report to CMS the outcome of case management via OMS and any associated coverage limitation information into MARx. CMS estimates that it will take sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually x 0.0167 hr) at a cost of $149 (2.6386 hr x $56.34/hr).

Table H5 summarizes the burden associated with the mandatory DMP provision.

TABLE H5: SUMMARY FOR MANDATORY DMPs

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153	Creating DMP	79	79	320	25,280	119.49	3,020,707	0
§ 423.153	Upload Model Notices	79	79	5	395	89.06	35,179	0
§ 423.153	Conduct Case Management	79	158	5	790	109.55	86,545	86,545
§ 423.153	Send Model Notices	8	8	0.1667	1.3336	56.34	75	75
§ 423.153	Report to CMS	79	158	0.0167	2.6386	56.34	149	149
TOTAL		79	482	varies	26,469	varies	3,142,655	86,769

CMS received no comments on the proposed burden estimates and assumptions. In the proposed rule, CMS had estimated the cost associated with case management of PARBs by combining the wage for all of the case management team members into one unit of case management time with the associated wage being the total of wages for the entire case management team to carry out case management ($547.74). This was reflected as 1 hour of

burden in the proposed rule. While this intermediate presentation did not ultimately affect the estimate of cost associated with case management, CMS realized that this was not an accurate representation of the true time associated with case management. Case management of each of the 158 PARBs requires 5 hours of work (2 from a pharmacist, 2 from a health technician and 1 from a physician). Therefore, CMS is revising the burden calculations for case management to reflect 5 hours of burden and calculated the case management team's hourly wage, prorated according to the number of hours contributed by each team member ($109.55). CMS is revising the number of hours from 158 to 790 (158 PARBs x 5 hr) as this is more accurate. It should be noted, however, that the total cost estimates associated with case management does not change between the proposed rule and this final rule. CMS is finalizing everything else without modification.

3. ICRs Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

The following changes will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

In this rule, CMS is finalizing the proposed changes to §423.153(f)(16) to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors as required by section 2006 of the SUPPORT Act. As a result of this requirement, additional beneficiaries will be reported by OMS as PARBs meeting CMS' proposed criteria for having a history of opioid-related overdose. In producing the estimates below, the burden per affected enrollee for case management (5 hr/response), notification of enrollees (10 min/response), and report to CMS (1 min/response) are identical with those estimated in section VIII.B.2. (ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)) of this final rule. That is, the overall burden associated with management of each PARB is the same whether the PARB is identified based on the current clinical guidelines or the updated clinical

guidelines which include the criteria for identifying PARBs with a history of opioid-related overdose. The updated clinical guideline criteria to incorporate history of opioid-related overdose increase the total number of beneficiaries identified and included in DMPs. The estimates that follow outline the burden associated with these additional PARBs.

Model beneficiary notices[89] provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, will need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal. CMS estimates it will take no more than 1 hour at $56.34/hr for a health technician to draft and implement such changes. In aggregate, CMS estimates a one-time burden of 288 hours (288 parent organizations x 1 hr/response) at a cost of $16,226 (288 hr x $56.34/hr).

Based on July 2017 through June 2018 opioid-related overdose data, CMS's internal analysis estimates that about 18,268 enrollees meet the criteria of an opioid-related overdose and would be PARBs. All of these PARBs will require case management. Using the wage and cost data outlined for the case management team in Table H4, in aggregate, CMS estimates an annual burden of 91,340 hours (5 hr x 18,268 PARBs) at a cost of $10,006,297 (91,340 hr x $109.55/hr).

In order to estimate the number of beneficiary notices needed to be sent, CMS compared two populations: (1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS estimates as 22,516 PARBs, based on internal data); and (2) beneficiaries

[89] Notice documents available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip

with a history of opioid-related overdose (which CMS estimates as 18,268 PARBs, based on internal data). CMS believes the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors, due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event.[90] CMS estimates that about 47.5 percent or 8,677 beneficiaries (18,268 beneficiaries x 0.475) of this population will receive an initial notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Thus, the beneficiary will also receive a second or alternate second notice informing them whether the limitation was in fact implemented. CMS estimates it will take 10 minutes (0.1667 hr) at $56.34/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden of 1,446 hours (8,677 enrollees x 0.1667 hr) at a cost of $81,468 (1,446 hr x $56.34/hr). Evaluation of the use of point-of-sale (POS) claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, CMS does not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, CMS recognizes that this change is projected to approximately double the number of beneficiaries CMS identifies to sponsors as PARBs.

With respect to the reporting of DMP data to CMS for PARBs identified based on history of opioid-related overdose, CMS estimates it will take sponsors (on average) 1 minute (0.0167

[90] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193-1201. doi: 10.1111/add.13774.

hr) at $56.34/hr for a health technician to report in OMS and/or MARx the outcome of case management and any applicable coverage limitations. In aggregate, CMS estimates an annual burden of 305 hours (18,268 PARBs x 0.0167 hr) at a cost of $17,184 (305 hr x $56.34/hr).

Table H6 summarizes the burden associated with the inclusion of PARBs with a history of opioid-related overdose in DMPs.

TABLE H6: SUMMARY FOR IDENTIFICATION OF ADDITIONAL PARBs BASED ON HISTORY OF OPIOID-RELATED OVERDOSE

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153(f)(16)	Revise Model Notices	288	288	1	288	56.34	16,226	0
§ 423.153(f)(16)	Conduct Case Management	288	18,268	5	91,340	109.55	10,006,297	10,006,297
§ 423.153(f)(16)	Send Model Notices	288	8,677	0.1667	1,446	56.34	81,468	81,468
§ 423.153(f)(16)	Reporting to CMS	288	18,268	0.0167	305	56.34	17,184	17,184
TOTAL		288	45,501	*Varies*	93,379	*Varies*	10,121,175	10,104,949

We received no comments on our proposed burden estimates and assumptions. In the proposed rule, CMS had estimated the cost associated with case management of PARBs by combining the wage for all of the case management team members into one unit of case management time with the associated wage being the total of wages for the entire case management team to carry out case management ($547.74). This was reflected as 1 hour of burden in the proposed rule. While this intermediate presentation did not ultimately affect the estimate of cost associated with case management, CMS realized that this was not an accurate representation of the true time associated with case management. Case management of each of

the 18,268 PARBs identified based on the definition of opioid-related overdose requires 5 hours of work (2 from a pharmacist, 2 from a health technician and 1 from a physician). Therefore, CMS is revising the burden calculations for case management to reflect 5 hours of burden and calculated the case management team's hourly wage, prorated according to the number of hours contributed by each team member ($109.55). CMS is revising the number of hours from 18,268 to 91,340 (18,268 PARBs x 5 hr) as this is more accurate. It should be noted, however, that the total cost estimates associated with case management does not change between the proposed rule and this final rule. We are finalizing everything else without modification.

4. ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amended section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs when furnishing an in-home health risk assessment. Section 1852(n)(2) requires CMS to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances. In order to implement the requirements of section 1852(n)(1) for MA plans, CMS revised the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2022, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with section 1852(n)(1), we proposed that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we proposed that MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We proposed that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the

enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we did not propose to require MA plans to provide more specific instructions with respect to drug disposal, we did propose that the communication to enrollees would provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also proposed that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html. We noted in our proposed rule that the safe disposal of drugs guidance at this website can be used for all medications not just medications that are controlled substances. We stated in our proposed rule that we believed that plan communications consistent with the standard on this website would furnish enrollees with sufficient information for proper disposal of controlled substances in their community.

The statute specifically limited this educational requirement to those situations when MA plans elect to perform in-home health risk assessments (HRAs) of MA enrollees. We note that

while SNP plans are required to perform enrollee health risk assessments all other MA plan types are not required to perform health risk assessments. In addition, SNPs may conduct HRAs over the phone. Since the performance of in-home of in-home heath risk assessment is not a specific requirement for MA plans we do not track or have data on the number of in-home HRAs that MA plans elect to perform. As we will further discuss while there is a burden imposed by the law and our regulation MA plans can almost entirely avoid this burden by choosing to not perform an in-home HRA. As previously discussed the burden for an MA plan when electing to conduct an in-home HRA is that consistent with CMS guidelines as previously described it must develop written guidance for the enrollee and also furnish when possible a verbal summary of the main options for the safe disposal of unused controlled medications.

5. ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

The following changes will be submitted to OMB for approval as a reinstatement under control number 0938-10396 (CMS-1154). We received one comment in response to our proposed changes. A summary of this comment, along with our response, is provided below.

In developing the burden estimates for this final rule, we removed the exclusion of beneficiaries enrolled in the Part D Enhanced MTM model because it will end before 2022, and the deadline for plans to come into compliance with the new Part D MTM program requirements finalized in this rule is January 1, 2022.

Since the inception of the Medicare Part D benefit, the Act has required that all Part D plans offer a MTM program to eligible beneficiaries. The Act also established criteria for targeting beneficiaries for MTM program enrollment and a minimum set of services that must be included in MTM.

Under § 423.153(d), all MTM enrollees must be offered a Comprehensive Medication Review (CMR) at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a

pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM, and added a requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees. This final rule modifies our Part D regulations to incorporate those changes to the MTM requirements. The new requirements will affect the number of beneficiaries enrolled in MTM programs and potentially some of the content for the Standardized Format for the CMR and, therefore, the burden. In this regard, we are estimating burden for:

a. The expanded population of beneficiaries that must be targeted for enrollment in MTM programs;

b. Mailing safe disposal information as part of the CMR summary; and

c. Mailing safe disposal information once a year as part of a TMR or other MTM correspondence or service.

a. The Expanded Population of Beneficiaries that Must Be Targeted for Enrollment in MTM Programs

We estimate that in 2022 there will be 50,684,424 beneficiaries enrolled in Part D plans with MTM programs (line 1 of Table H7). According to internal data, we estimate that section 6064 of the SUPPORT Act requires targeting 10,366 ARBs for MTM in 2022 (line 2). Based on our experience with the MTM program, we estimate that 71.8 percent of beneficiaries targeted for MTM under the existing requirements will accept the offer of a CMR (line 3). This number has been updated based on more recent data which became available after the proposed rule was published. We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 7,443 ARBs (line 4) (10,366 targeted ARBs x 0.718) are expected to accept a CMR under the new provision.

To estimate the burden on Part D plans of furnishing CMRs to the 7,443 ARBs who would be expected to accept the offer of a CMR under the final policy, we separately calculate the labor cost of preparing the CMR and packaging it, and the non-labor cost of mailing.

To estimate the labor cost of preparing the CMR, we note that the CMR is a clinical consultation service and therefore must be administered by a pharmacist, physician, nurse practitioner, or other qualified provider. Currently, 100 percent of MTM programs employ pharmacists to conduct CMRs, which is the basis of the hourly rate estimate. Stakeholder comments that were received outside of this rulemaking effort and responded to in a previous collection of information request indicate that an average CMR requires 40 minutes or 0.6667 hours (line 5) at $120.68/hr (line 7) for a pharmacist to complete. This results in an annual labor burden of 4,962 hours (line 6) (7,443 ARBs x 0.6667 hr) at a cost of $598,814 (line 8) (4,962 hr x $120.68/hr).

To estimate the cost of mailing, we note that paper costs $2.50 per ream (500 sheets) of paper (at $0.005 per sheet) and toner costs $50.00 per cartridge and lasts for 10,000 sheets (at $0.005 per sheet). We estimate that the average CMR summary will be 6 pages in length based on revisions which would streamline the Standardized Format; therefore, the paper and printing costs for each CMR summary will be $0.06. Since CMR summaries contain private health information, they must be mailed first class, for which postage costs $0.70 per mailing. Based on industry standards, we assume envelopes cost $0.08 each, while folding and stuffing costs about $0.08 per document. We therefore estimate the non-labor cost to print and mail a CMR summary in CMS's Standardized Format will be $0.92 per mailing (line 9). This results in a cost of $6,848 (line 10) ($0.92 cost per mailing x 7,443 ARBs).

Therefore, we estimate that the total annual cost of providing CMRs to 7,443 ARBs is $605,662 (line 11) ($598,814 labor costs + $6,848 non-labor mailing costs). These figures and calculations are summarized in Table H7. The Line ID column contains identifiers for each row

following the flow of logic and calculations. Where applicable, the calculations are described in the "Source" column.

TABLE H7: ESTIMATED BURDEN OF TARGETING ARBs FOR MTM

Line ID	Item	Number	Source
(1)	Part D enrollees in 2022	50,684,424	Internal CMS Data
(2)	Part D enrollees expected to meet the ARB criteria	10,366	Internal CMS data
(3)	Percent of enrollees under the existing program targeted for a CMR who accept the offer	71.8%	Internal CMS data
(4)	ARBs targeted for MTM expected to accept CMR offer	7,443	(2)*(3)
(5)	40 minutes is the industry standard for conducting a CMR	0.6667	Industry data
(6)	Number of hours needed to fulfill the preparation of CMRs under the new provision including stuffing and mailing	4,962	(4)*(5)
(7)	Wage for a pharmacist to prepare a CMR	$120.68	BLS Wage data
(8)	Cost to send CMRs to ARBs under the new provision	$598,814	(6)*(7)
(9)	Non-labor cost of mailing one CMR: 6 pages * ($2.50*500 cost per page + $50/10000 cost of toner)+ $0.08 stuffing + $0.08 envelope + $0.70 for postage	$0.92	See narrative
(10)	Non-labor cost of mailing	$6,848	(8)*(9)
(11)	Total cost for preparing and mailing the CMR to ARBs	$605,662	(8)+(10)

b. Mailing Safe-Disposal Information as Part of the CMR Summary

Under the revisions to § 423.153(d)(1) adopted in this final rule, Part D plans will be required to provide all MTM enrollees with information about safe disposal of prescription medications that are controlled substances. The provision will allow plans to mail the newly required safe disposal information either as part of the CMR summary, a TMR, or other MTM correspondence or service. We estimate the safe disposal information will take one page, may include personal information, and can be mailed out as a standalone correspondence if not included in the annual CMR.

However, for those enrollees receiving a CMR, we believe it will be most economical to include the one page with the already existing CMR summary. We solicited comments regarding this assumption, but did not receive any feedback. Therefore, we are estimating that

the cost of mailing one extra page per enrollee is $0.01 (line 21 ([1 page x $2.50 / ream of 500 sheets] + [1 page x $50 toner/10,000 sheets]). We note that the envelope to mail the CMR is already being paid for under current regulations (although folding and stuffing of 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost estimate and we did not receive any comments on this assumption); the $0.70 first class postage for 2 ounces is sufficient for 7 pages (there would be no increase in postage).

To estimate total mailing cost, we add the estimates of i) total number of Part D enrollees who are not ARBs who will receive a CMR under the existing criteria and ii) total number of ARBs who will receive a CMR under the new criteria we are adopting in this final rule.

As shown in Table H7, lines (1) and (2), we estimate that in 2022 there will be 50,684,424 Part D enrollees and, as previously determined, 10,366 of those will meet the new MTM targeting criteria, leaving 50,674,058 Part D enrollees (Table H8, line 14) (50,684,424 Part D enrollees minus 10,366 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the existing criteria. Our internal data shows that 6.54 percent (line 15) of Part D enrollees will be targeted for MTM programs under the existing criteria. Hence, this leaves 3,314,083 Part D enrollees (0.0654 * 50,674,058) who will be targeted for MTM under the existing criteria (line 16). Of the 3,314,083 targeted enrollees, as stated previously, based on internal CMS data, we estimate 71.8 percent will accept the annual CMR offer (line 17). Therefore 2,379,512 beneficiaries (3,314,083 * 0.718) will receive a CMR under the existing criteria (line 18).

Hence, in 2022 a total of 2,386,955 enrollees will receive a CMR under the existing and new criteria (7,443 ARBs under the new criteria + 2,379,512 under the existing criteria) (line 20), at a total non-labor mailing cost of $23,870 (2,386,955 enrollees x $0.01 mailing cost per enrollee) to add an additional page containing safe disposal information to all CMRs (line 22).

The figures and calculations are summarized in Table H8.

TABLE H8: ESTIMATED BURDEN FOR MAILING SAFE DISPOSAL INFORMATION AS PART OF THE CMR

Line ID	Item	Number	Source
(12)	Part D enrollees in 2022	50,684,424	(1)
(13)	Enrollees estimated to meet ARB criteria under the new provision	10,366	(2)
(14)	Part D enrollees who do not meet ARB criteria	50,674,058	(12)-(13)
(15)	Percentage of Part D enrollees who meet the existing criteria for MTM	6.54%	Internal CMS data
(16)	Estimated number of Part D enrollees not meeting ARB criteria who are targeted for MTM under the existing criteria	3,314,083	(14)*(15)
(17)	Percent of enrollees under the current program targeted for an MTM who accept the offer	71.8%	Internal CMS data
(18)	Estimated number of Part D enrollees under the existing criteria who will receive a CMR	2,379,512	(16)*(17)
(19)	Estimated number of Part D enrollees under the new provision meeting ARB criteria who will elect to receive a CMR	7,443	(4)
(20)	Total number of Part D enrollees (under the existing and new criteria) who will receive a CMR	2,386,955	(18)+(19)
(21)	Non-labor costs of one extra page (2.50/500) and toner for one page ($50/10000)	$0.01	See narrative
(22)	Estimated cost of mailing safe disposal information with a CMR	$23,870	(20)*(21)

c. Mailing Safe Disposal Information Once a Year as Part of a TMR or Other MTM Correspondence or Service

All targeted beneficiaries who have not opted out of the MTM program must receive TMRs at least quarterly, and we are allowing Part D sponsors the flexibility of choosing whether to include safe disposal information in the CMR, through a TMR or other MTM correspondence or service at least once annually. Since we assume that 71.8 percent of targeted enrollees accept an offer of a CMR (Table H7, line 3), it follows that 28.2 percent (100 percent – 71.8 percent) (Table H9, line 26) of Part D enrollees who are targeted for enrollment in an MTM program refuse the CMR offer but do not opt out of the MTM program completely. As discussed previously, 10,366 ARBs (Table H7, line (2)) under the new criteria and 3,314,083 enrollees (Table H8, line (16)) under the existing criteria, for a total of 3,324,449 enrollees (3,314,083 + 10,366) (line 25) will be targeted to receive a CMR. Therefore 937,495 enrollees (3,324,449 total enrollees x 0.282 who refuse a CMR) would need to be mailed the safe disposal information as

part of a TMR or other MTM correspondence or service (line 27). For purposes of calculating the burden, we are assuming that any safe disposal information that is not included in a CMR is either i) being mailed in a TMR, which may be as short as one page and may contain private health information or ii) is mailed as a stand-alone document which does not contain any private health information. For purposes of impact, i) if one additional page is included in the TMR, then there is no additional postage; ii) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data in regard to what percentage of safe disposal information will be mailed as a CMR, TMR, or other MTM correspondence or service, we are assuming the maximum amount, which is that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage. The cost to mail one page of safe disposal information is $0.01095 per enrollee if the letter does not contain private health information and thus bulk mailing is used (line 28) [1 page x $2.50 per ream of paper / 500 sheets] + [1 page x $50 per toner / 10,000 pages] + [$0.19 / 200 items]). Therefore, we estimate that the cost of mailing safe disposal information to those MTM enrollees who do not receive it in a CMR summary is $10,266 (line 29) (937,495 enrollees x $0.01095 mailing cost per page).

These calculations are summarized in Table H9.

TABLE H9: BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO ENROLLEES NOT RECEIVING A CMR

Line ID	Item	Number	Source
(23)	The number of Part D enrollees who meet the existing criteria for MTM	3,314,083	(16)
(24)	The number of Part D enrollees who meet the criteria for ARB under the new provision	10,366	(2)
(25)	The number of Part D enrollees meeting existing or new criteria for being targeted for a CMR	3,324,449	(23)+(24)
(26)	The percentage of enrollees estimated to refuse the offer of a CMR (100-87%)	28.2%	100% - (17)
(27)	Number of enrollees to whom safe disposal information must be mailed even though they don't receive a CMR	937,495	(25)*(26)
(28)	Non-labor cost of mailing a one page correspondence (at $2.50/500 cost per page	$0.01095	See narrative

	+ $50/10,000 cost of toner for one page + $0.19/200 cost of bulk mailing)		
(29)	Cost of mailing safe disposal information to those who do not receive a CMR	$10,266	(27)*(28)

d. Summary for Eligibility for MTMPs and Information on the Safe Disposal of Prescription Drugs

As discussed in section (b) (Table H8, line (22)), we estimate a cost of $23,870 for mailing safe disposal information to those beneficiaries receiving a CMR (under the assumption that the plan will bundle the safe disposal and CMR). In section (c) (Table H9, line 29), we estimate a total cost of $10,266 for mailing safe disposal information to those beneficiaries who do not receive a CMR. Thus, the total cost of mailing safe disposal information to all Part D beneficiaries enrolled in MTM programs is estimated to be $34,136. This is summarized in Table H10.

TABLE H10: BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO BENEFICIARIES ENROLLED IN MTM PROGRAMS

Line ID	Item	Number	Source
(30)	Estimated cost of mailing safe disposal items to those receiving a CMR (under assumption that the plan will bundle the safe disposal and CMR)	$23,870	(22)
(31)	Cost of mailing safe disposal to those who do not receive a CMR	10,266	(29)
(32)	Total cost of mailing safe disposal information	$34,136	(30)+(31)

The total additional annual cost for 288 parent organizations to provide CMRs to ARBs and to send information on safe disposal of prescription medications that are controlled substances to all MTM program enrollees is $663,668. Table H11 provides a compact summary of the bottom lines of impact by activity.

TABLE H11: SUMMARY FOR ELIGIBILITY FOR MTMPs (§ 423.153) AND INFORMATION ON THE SAFE DISPOSAL OF PRESCRIPTION DRUGS

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Non labor Cost for Mailing ($)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Targeting ARBs for CMR	288	7,443	0.6667	4,962	N/A	120.68	598,814
§ 423.153	Mailing ARBs CMR	288	7,443	N/A	N/A	6,848	N/A	6,848
§ 423.153	Safe Disposal Page in CMR	288	2,386,995	N/A	N/A	23,870	N/A	23,870
§ 423.153	Safe Disposal Page as part of TMR or other MTM correspondence or service	288	937,495	N/A	N/A	10,266	N/A	10,266
TOTAL		288	3,339,376	Varies	4,962	40,984	Varies	639,798

As indicated above, one PRA-related comment was received. The following summarizes the comment and sets out our response.

Comment: CMS received a comment stating that the percent of Part D enrollees who accept the offer of a CMR (87 percent) was overestimated.

Response: We appreciate the comment and have updated our estimate based on more recent data. We are now estimating the acceptance rate of a CMR to be closer to 71.8 percent in 2022.

As previously stated, we updated our estimates to no longer exclude beneficiaries enrolled in the Part D Enhanced MTM model because the model will end before 2022, and the deadline for plans to come into compliance with the new Part D MTM program requirements finalized in this rule is January 1, 2022. We also updated the estimates for enrollment and CMR

rates based on more current data. We did not receive any comments in response to our estimates regarding the cost of mailing a CMR with information on safe disposal of prescription drugs, nor did stakeholders object to our assumption that the distribution of information on safe disposal of prescription drugs would be most economically distributed as part of the CMR summary.

6. ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The following changes will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

With regard to our proposed changes, comments were received and are responded to below.

In this rule, § 423.128 will require Part D sponsors to disclose, beginning in 2022, information about the risks of prolonged opioid use to enrollees. In addition to this information, Part D sponsors of MA-PDs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Part C. Part D sponsors of PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Before Part D sponsors can send this information, they would have to create and upload materials into their internal systems. Based on 2019 CMS data, there are 608 Part D legal entities (sponsors) with which CMS contracts, associated with 288 parent organizations that these contracts identified in their initial applications, which is confirmed annually. Based on our knowledge of the way parent organizations and their Part D legal entities are structured, we believe it is appropriate to estimate burden at the parent organization level, as it is a closer reflection of the number of systems that will need to be updated versus at the contract level.

We estimate that 288 Part D sponsors would be subject to this requirement, based on 2019 data. We estimate a one-time burden of 2 hours at $120.68/hr for a pharmacist to develop

the materials(s) to be sent to the beneficiaries. In aggregate, we estimate a one-time burden of 576 hours (288 parent organizations x 2 hr) at a cost of $69,512 (576 hr x $120.68/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), we believe the burden to making such updates to existing materials will be negligible as the changes will be minor and may only occur in some future years. Hence, the more accurate approach adopted here is to estimate this as a one-time update.

We also estimate that it will take on average 2 hours at $89.06/hr for a computer programmer to upload the information into the systems. This would result in a one-time burden of 576 hours (2 hr x 288 parent organizations) at a cost of $51,299 (576 hr x $89.06/hr). Once the information is uploaded into the parent organization's database, we anticipate no further burden associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The automation will include the sending of information to those enrollees who wish to receive an electronic copy. The automation will also cover updates in future years as the plan enrollment changes.

We proposed that Part D sponsors be permitted to disclose the opioid and coverage information in electronic form. Some enrollees preferred electronic notification and some preferred paper mailing. We had no way of estimating the proportions for each preference, but our experience suggests that most enrollees expect a paper mailing. Therefore, we assumed 75 percent (the average of 50 percent and 100 percent) would prefer a paper mailing, while the remaining 25 percent would prefer electronic notification.

There are several Part D enrollee groups presented in section III.D. of this final rule that we suggested could be sent the required information and thus, several approaches to estimate the burden. These enrollee group estimates ranged from sending the information to 2,698,064 to 46,759,911 enrollees.

In making estimates on the burden of sending out notices, we assumed that the IT systems of the plan would generate and mail the documents once a template is produced. Thus,

the only costs are paper, toner, and postage. We also assumed one page per notice. We therefore estimate:

• Cost of paper: Typical wholesale costs of paper are approximately $2.50 for a ream of 500 sheets. The cost for one page is $0.005 ($2.50 / 500).

• Cost of toner: Toner costs can range from $50 to $200 and each toner cartridge can last from 4,000 to 10,000 sheets of paper. In this rule, we assume a cost of $50 for 10,000 pages. In that regard, the cost per page is $0.005 ($50 / 10,000 pages).

• Cost of postage: Currently, the bulk postage rates are $0.19 per 200 pages. The cost per page is $0.00095 ($0.19 / 200 pages).

Thus, the aggregate cost per page is $0.01095 ($0.005 for paper + $0.005 for toner + $0.00095 for postage). Note that mailing costs are annual while the programming updates and the development of materials are first-year costs with minimal or no costs in future years. The product of the cost per page (at $0.01095) times the number of enrollees (35,069,933) plus the one time first year costs $120,811 ($51,299 + $69,512) equals $504,827 ([$0.01095 x 35,069,933 enrollees] + $120,811) as shown in Table H12.

TABLE H12: IMPACTS FOR PROVIDING INFORMATION TO OPIOID USERS

Item Description	Number of respondents	Number of Responses	Time per response (hr)	Total time (hr)	Non Labor Costs for mailing ($)	Labor cost ($/hr))	First year cost ($)	Cost in subsequent years ($)
Programming	288	288	2	576	NA	89.06	51,299 (Labor)	N/A
Pharmacist development of the materials	288	288	2	576	NA	120.68	69,512 (Labor)	N/A
75% of All Part D enrollees who are estimated to want paper	288	35,069,933	N/A	N/A	384,016	N/A	384,016 (Non Labor)	384,016 (Non Labor)
Total	288	35,070,509	varies	1,152	384,016	Varies	504,827	384,016

The following summarizes the PRA-related public comments that we received and sets out our response to those comments. We are finalizing our proposed provisions, burden estimates, and assumptions without change.

Comment: We received two comments that suggested a specific subset to send this information to. The commenters also recommended focusing on any beneficiary who received an opioid fill in the last 7 days, but also appreciated the flexibility provided in this rule.

Response: We thank the commenters for their feedback. Although some commenters offered their opinion on the subset that might be the best group to receive the information, there was no consensus to inform sponsors' ultimate decisions on a specific enrollee population. Because there was no consensus, CMS will continue to maintain flexibility for plans and therefore are not committing to any specific approach.

7. ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

The following changes will be submitted to OMB for approval under control number 0938-1383 (CMS-10724) for Medicare Advantage Plans and 0938-1262 (CMS-10517) for Part D Plans.

Sections 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) will require the MA organization or Part D plan sponsor, respectively, to have procedures to identify and report to CMS or its designee: (1) any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and (2) any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

CMS initiated a reporting pilot program in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste, and abuse. The pilot collected all external or internal Medicare complaints and referrals submitted to the plan's Special Investigations Unit (SIU). The data collected as part of the pilot program was time limited, but broader than the scope of reporting required by sections 2008 and 6063 of the SUPPORT Act. The scope of that pilot tested the reporting of all types of health care fraud, waste, and abuse that the plan sponsors could encounter in their operations and, therefore, could be utilized as a reasonable estimate of burden involved with the quarterly plan reporting to CMS that CMS will use to implement sections 2008 and 6063 of the SUPPORT Act. The pilot program analyzed information that was reported from five of six plan participants on time spent collecting three quarterly data submissions. Based on the results of the pilot study, if every Part C plan reported, we estimate it will take 605 MA plans 149,435 hours (605 plans * 247 hr/plan) at a cost of $13,730,088 (149,435 hr * $91.88/hr for a management analyst using 2019 BLS wage estimates) to fulfill the reporting and procedure preparation in the first year as shown in Table H13. In subsequent years, we estimate an annual burden of 94,380 hours (605 plans *156 hr/plan) at a cost of $8,671,634(94,380 hr * $91.88/hr) as shown in Table H13.

Based on the results of the pilot study, if every Part D plan reported, we estimate it will take 63 Part D plans 15,561 hours (63 plans * 247 hr/plan) at a cost of $1,429,745 (15,561 hr * $91.88/hr) to fulfill the reporting and procedure preparation in the first year as shown in Table H14. In subsequent years, we estimate an annual burden of 9,828 hours (63 plans * 156 hr/plan) at cost of $902,997 (9,828 hr * $91.88/hr) as shown in Table H14.

The first-year burden consist of the time and effort needed to prepare the procedures and report the inappropriate prescribing information. Subsequent effort consists solely of the ongoing time and cost to report the inappropriate prescribing information to CMS. We could not anticipate how many plans will need to report any payment suspension to pharmacies in the plans' network or information on inappropriate opioid prescribing to CMS.

TABLE H13: MA ORGANIZATION BURDEN ESTIMATES

Regulatory Citation	OMB Control Number	Response Summary	Total Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
§ 422.503(b)(4)(vi)(G)(*4*)	0938-1383	Report fraud and abuse	605	605	247	149,435	91.88	13,730,088	0
§ 422.503(b)(4)(vi)(G)(*4*)	0938-1383	Report fraud and abuse	605	605	156	94,380	91.88	0	8,671,634
TOTAL*			605	1,210	varies	243,815	91.88	13,730,088	8,671,634

TABLE H14: PART D PLAN SPONSOR BURDEN ESTIMATES

Regulatory Citation	OMB Control Number	Response Summary	Total Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
§ 423.504(b)(4)(vi)(G)(*4*)	0938-1262	Report fraud and abuse	63	63	247	15,561	91.88	1,429,745	0
§423.504(b)(4)(vi)(G)(*4*)	0938-1262	Report fraud and abuse	63	63	156	9,828	91.88	0	902,997
TOTAL			63	126	varies	25,389	91.88	1,429,745	902,997

We received no comments on our proposed provisions, burden estimates, and assumptions. Consequently, we are finalizing without change.

8. ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

The following changes will be submitted to OMB for approval under control number 0938-0763 (CMS-R-262). Subject to renewal, the control number is currently set to expire on April 30, 2022.

As described in section IV.G. of this final rule, the new paragraphs at § 423.128(d)(4) and (5) require each Part D plan to implement a beneficiary RTBT no later than January 1, 2023.

This tool will allow enrollees to view the information included in the prescriber RTBT system which includes complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). Plans will be able to use existing secure patient portals to fulfill this requirement, to develop a new portal, or to use a computer application.

In estimating the cost impact of this provision it is important to bear in mind that the rewards and incentives are optional for each Part D sponsor. Additionally, based on our conversations with the industry, participation on industry workgroups, and research, we understand that most Part D plans have already created beneficiary portals that satisfy existing privacy and security requirements. We believe that the few plans that have yet to create a portal or web application will have one in place by January 1, 2023. Finally, some Part D Sponsors who wish to use such a portal may find it cheaper to rent an existing portal from a third party vendor. Consequently, the impacts below are maximum impacts; they overestimate the impact of the provision by assuming that all Part D sponsors must create a completely new RTBT.

We estimate it will take 104 hours at $89.06/hr for a computer programmer to program this information into the beneficiary portal and an additional 52 hours to put this information into a user interface that is easily understood by enrollees. The time estimates are based on consultation with the healthcare industry and their IT staff to determine the time that it takes for minor changes in programming. Thus, the burden for implementing RTBT is 44,928 hours (288 organizations * 156 hr) at a cost of $4,001,288 (44,928 hr * $89.06/hr).

This is a maximum one-time first year cost. We are not estimating ongoing maintenance costs because: 1) Many plan sponsors already have a beneficiary portal and 2) the total maintenance costs per plan sponsor tend to be stable from year because although there is variation in what software needs maintenance, some software needs more usage, some needs less, and some needs routine. The average absorbs and stabilizes this variability. Adding one

more software cost that is not excessively above the average would not change that average beyond rounding or uncertainty error.

We next estimated the cost of implementing the rewards and incentives program for use of RTBT. We estimated three items: A) Development of policies for the new program, B) updating of systems, and C) maintaining the program. We solicited stakeholder feedback on all of our proposed assumptions. We informally questioned stakeholders who believe that only 10 percent of parent part D sponsors would create such a program. Since there are 288 Part D sponsors we expect 29 (288 * 0.10) organizations to develop and use a reward and incentive program.

A) Development of policy: We estimate that for each parent organization an operations manager and compliance officer working together at a combined hourly wage of $188.36/hr ($118.30/hr + $70.06/hr) would take 40 hours. Therefore, the impact is 1,160 hours (40 hr * 29 parent organizations) at a cost of $218,498 (1,160 hr * $188.36/hr).

B) Since systems already exist to collect enrollee data, they will only have to be updated to collect data on use of RTBT and most of this work will be done when creating the RTBT. We therefore estimate, per parent organization, an extra 40 hours for a computer programmer. Therefore, the impact is 1,160 hours (40 hr * 29 organizations) at a cost of $103,310 (1,160 hr * $89.06/hr).

C) We estimate that 2 administrative support workers each working at $36.82/hr will take 15 hours every month to maintain the program. The impact is 10,440 hours (15 hr/month * 12 months * 2 workers * 29 organizations) at a cost of $384,401 (10,440 hr * $36.82/hr).

The aggregate impact for implementing the rewards and incentives for RTBT among those Part D sponsors who wish to do so is 57,688 hours (44,928 hr + 1,160 hr + 1,160 hr + 10,440 hr) at a cost of $4,707,497 ($4,001,288 + $218,498 + $103,310 + $384,401).

Since plans are in the best position to estimate their implementation costs, we solicited comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility for enrollees. In addition, because plans are in the best position to estimate any information collection implications, since they will be the stakeholders implementing this provision, we solicited comment on any other potential information collection implications. We received no comments on our proposed provisions and burden estimates. Consequently, we are finalizing them without change.

9. ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

The following changes will be submitted to OMB for approval under control number 0938-0992 (CMS-10185). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 7, 2018, and remains active.

This rule amends § 423.514(a) by giving CMS the authority to collect Part D sponsors' pharmacy performance measures data that is used to evaluate pharmacy performance, as established in their network pharmacy agreement. Given the growing practice of Part D sponsors measuring the performance of pharmacies that service Part D beneficiaries to determine the final cost of a drug under Part D, this reporting requirement will enable CMS to monitor the impact of these recoupment practices. We estimate a collection of less than 15 data elements. As noted in section IV.G of this final rule, the Part D reporting requirements data elements, consistent with our standard, will be specified through the standard non-rule PRA process after publication of this final rule. The standard non-rule process includes the publication of 60- and 30-day **Federal Register** notices. At that time, the data elements, timeline, and method of submission will be made available for public review and comment.

Although the data elements will be made available for public review through the standard PRA process, we are providing the interested parties with an initial projection of the potential burden estimates. In this regard there are currently 627 contracts that would be required to report

their pharmacy performance measures' data. Part D sponsors currently report 6 sections of data to CMS in accordance with the Part D reporting requirements. Therefore, CMS does not expect compliance to these reporting requirements will result in additional start-up costs. Anticipated staff time spent performing these data collection activities would be 30 minutes for a data analyst and/or IT analyst at a rate of $92.46/hr. We will require this information to be reported at the plan level once annually. Reporting at the plan level would generate 5,234 responses since there are currently 5,234 plans. In aggregate, we estimate an annual plan sponsor burden of 2,617 hours (5,234 plans x 1 report/year x 0.5 hr/report) at a cost of $241,968 (2,617 hr x $92.46/hr). We solicited input from stakeholders on the accuracy of these estimates and on any measures that CMS could take to decrease the burden of this provision. The following comment was received.

Comment: We received one comment stating that we had underestimated the financial burden of Part D plans reporting their pharmacy collection measures.

Response: We appreciate the comment. However, we believe that based on current wages from the Bureau of Labor Statistics, and from our long current history of collecting other Part D plan reporting requirements, that our burden estimate is fair and reasonable.

We did not receive any other comments related to the projected burden for this provision. As a result, we are finalizing our proposed provisions and burden without change.

10. ICRs Regarding PACE

Subsequent to the publication of the proposed rule, we revised the burden estimates in this final rule by: (1) incorporating service determination request (formerly "service delivery request") data from 2019 PACE audits which was not available at the time the estimates were published in the proposed rule, (2) updating enrollment data from 40,040 participants to 42,800 participants based on 2017-2019 enrollment data from the CMS Office of the Actuary (OACT), (3) updating PACE organization contract data from 131 PACE organizations to 133 PACE

organizations based on data from the Health Plans Management System (HPMS), and (4) updating wage figures based on May 2019 BLS data.

The following changes in subsections 10a through 10e will be submitted to OMB for approval under control number 0938-0790 (CMS-R-244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

a. ICRs Regarding Service Determination Request Processes under PACE (§§ 460.104 and 460.121)

Section 460.121(i)(2) will require that PACE organizations provide written notification to participants when the interdisciplinary team extends the timeframe for processing service determination requests. Based on our experience with PACE audits during 2017, 2018, and 2019, during which time we reviewed all operating PACE organizations at least once, we found a total of 30,173 service determination requests. The average total PACE enrollment during that same period was 42,800. Thus the average number of service determination requests per 1,000 enrollees was 705 (30,173/42,800). This service determination request ratio or intensity (705 service determination requests per 1,000 enrollees) is used to estimate the number of service determination requests PACE organizations will receive from 2022-2024. The service determination request ratio is an intuitive way of capturing the rate of service determination requests per thousand enrollees and is used to estimate the burden associated with service determination requests for 2022-2024.

Based on the same audit experience and data collected, we further estimate that:

- Approximately 10.16 percent of all service determination requests currently received are extended, and
- Of those 705 service determination requests currently received per 1,000 enrollees, 77.53 percent are approved (546.6 requests per 1,000 enrollees), while 22.47 percent are denied (158.4 requests per 1,000 enrollees).

With respect to the final service determination request requirements in the new § 460.121, we estimate that half of all approved service determination requests (that is, 50 percent of the 546.6 approved requests per 1,000 enrollees or 273.3 requests per 1,000 enrollees) could be approved in full by an IDT member at the time the request is made. Because those approval decisions could be made immediately, extension notifications would not be needed for those service determination requests.

Therefore, the requirement to provide written notification when a service determination request is extended will apply to:

- The 2.28 percent of service determination requests which are extended and subsequently denied (22.47 percent of service determination requests that are denied * 10.16 percent of service determination requests that are extended); and
- The 3.94 percent of service determination requests that are approved and not routine (that is, a member of the IDT cannot approve the service determination request in full at the time the request is made) and are extended (77.53 percent of service determination requests that are approved * 50 percent of requests that are not routine * 10.16 percent of requests that are extended).

Thus the requirement will apply to 6.22 percent (2.28 percent of denied service determination requests and 3.94 percent of approved service determination requests) of all service determination requests. Based on OACT estimates, the average projected PACE enrollment for 2022-2024 is 53,549 per year or an increase of 10,749 enrollments from 2017 – 2019 (53,549 - 42,800). The multiplication of the estimated 2022-2024 PACE enrollment (53,549 enrollees) by the current service determination request intensity of 705 per 1,000 enrollees gives a reasonable estimate of the number of service determination requests PACE organizations will receive for 2022-2024. Based on our audit experience, we estimate that it would take the IDT approximately 1 hour to prepare and issue notification of the extension to a participant or the designated representative.

Consequently, the total annual burden for providing written notification to participants when the interdisciplinary team extends the timeframe for processing service determination requests in accordance with § 460.121(i)(2) is 2,350 hours (705 requests per 1,000 enrollees x 53,549 projected enrollment for 2022-2024 x 6.22 percent of requests that require extensions x 1 hour to process each service determination request extension) at a cost of $133,997 (2,350 hr x $57.02/hr for a Master's-level Social Worker (MSW) (BLS: healthcare social worker) to process them).

To meet the notification requirements finalized in § 460.121(i)(2), we expect most PACE organizations will develop a template letter to notify the appropriate parties of an extension. We estimate a burden of 1 hour at a cost of $70.06/hr for a compliance officer (quality improvement coordinator) to create an extension letter template.

In addition to the one-time burden associated with creating an extension letter template, we also anticipate a one-time burden associated with the requirements we are finalizing in § 460.121(j)(2), which clarify the required content of denial notifications. As a result of these requirements, we expect that PACE organizations will need to revise their denial notification letter templates. We estimate a burden of 1 hour at a cost of $70.06/hr for a compliance officer (quality improvement coordinator) to revise any existing denial letter templates.

In aggregate, for the development and revision of both the extension notification and denial notification, we estimate it will take of 2 hours at $70.06/hr for a compliance officer (quality improvement coordinator) to create and revise the materials. We estimate a one-time burden of 266 hours (133 PACE organizations x 2 hr) at a cost of $18,636 (266 hr x $70.06/hr).

We received no comments on our proposed burden estimates in §§ 460.121 and 460.104. In this final rule, we revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) service determination request data from 2019 PACE audits, (2) 2017-2019 enrollment data, (3) PACE organization contract data,

and (4) wage data. Based on this updated data, we have revised the burden estimate for service determination request extension notification in new § 460.121(j)(2), which resulted in a decrease of 578 hours (from 2,928 hr to 2,350 hr) and $30,615 (from $164,612 to $133,997) from the proposed rule. We have also revised the burden estimate for service determination request denial notification requirements in new § 460.121(i)(2), which resulted in an increase of 4 hours (from 262 hr to 266 hr) and $369 (from $18,267 to $18,636) from the proposed rule.

b. ICRs Regarding Appeals Requirements under PACE (§§ 460.122 and 460.124)

Section 460.122 currently states the requirements for implementing an appeals process in PACE. In this rule we are finalizing requirements for PACE organizations to develop and distribute written materials that will explain the PACE requirements to the third party reviewers that are responsible for making appeal determinations. Additionally, we are finalizing requirements for appeal decision notifications, which we expect will require PACE organizations to revise their current appeal notification materials.

For the development and distribution of materials to the third party reviewer, we estimate it will take 4 hours at $70.06/hr for a compliance officer (quality improvement coordinator) at each PACE organization to create and distribute these materials (3 hr to create and 1 hr to distribute). For the revision of the written appeal notices, we estimate it will take 1 hour at $70.06/hr for a compliance officer (quality improvement coordinator) at each PACE organization to revise the current notices.

In aggregate, we estimate a one-time burden of 665 hours [133 PACE organizations * (4 hr + 1 hr)] at a cost of $46,590 (665 hr * $70.06/hr).

We received no comments on our proposed burden estimates for this provision. In this final rule, we revised the burden estimate for developing and distributing written materials to third party reviewers using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimate includes: (1) 2017-2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated

service determination request data was not utilized to revise this burden estimate since the data does not impact appeals notifications. Based on the updated data, we have revised the burden estimate for this provision which resulted in an increase of 10 hours (from 655 hr to 665 hr) and $923 (from $45,667 to $46,590) from the proposed rule.

c. ICRs Regarding Documenting and Tracking the Provision of Services under PACE (§ 460.98)

As discussed in section VI.D. of this final rule, we are amending § 460.98(b)(5) in part to require PACE organizations to document, track and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care.

We estimate a one-time burden of 50 hours at $56.34/hr for technical staff at each PACE organization to develop the necessary procedures and written materials. We estimate a one-time burden of 6,650 hours (133 PACE organizations * 50 hr) at a cost of $374,661 (6,650 hr * $56.34/hr) for the first year. Since PACE organizations are currently required to document all services furnished in the medical record in accordance with § 460.210(b)(2), we believe the one-time burden of 50 hours is a reasonable estimate for developing the necessary procedures and written materials to document, track, and monitor the provision of services.

We also estimate this provision will result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about the documentation, tracking and monitoring of services, based on our experience monitoring and auditing PACE organizations.

As discussed above, PACE organizations are already required to document services furnished in the participant's medical record; however, PACE organizations will need to devote time to monitoring and tracking the provision of services. We therefore estimate a burden of 50 hours at $56.34/hr for technical staff to complete these activities, including, when warranted, revision of the aforementioned program procedures and monitoring measures. We estimate an

annual burden of 6,650 hours (133 PACE organizations * 50 hr) at a cost of $374,661 (6,650 hr * $56.34/hr).

In aggregate, we estimate a burden of 13,300 hours (6,650 hr + 6,650 hr) at a cost of $749,322 ($374,661 + $374,661) for the first year of implementation. In subsequent years, we estimate a burden of 6,650 hours at a cost of $374,661 for the ongoing documentation, monitoring and tracking of services.

We received the following comments on the estimated burden for this provision.

Comment: The majority of commenters expressed concern with to the use of the term "track." These commenters suggested that requiring a PACE organization to track the provision of services could imply that PACE organizations would be required to establish and maintain specific logs, universes or data sets, and that such a requirement would potentially increase burden and conflict with CMS' Patients Over Paperwork initiative.

Response: As we discussed in greater detail in section VI.D. of this final rule, we understand from commenters' concerns that the use of the word "track" could be interpreted to suggest that PACE organizations would be required to maintain a real time "log" of services which could potentially be burdensome to implement. As we stated in the proposed rule, we believe that PACE organizations should document that a service has been ordered as well as when and how the approved service was provided. It was not our intention in the proposal to dictate how an organization implements this provision, and we agree with the commenter that PACE organizations should have flexibility in how they operationalize the requirement to track, monitor and document the provision of services. We expect that PACE organizations will create their own methods for tracking and monitoring services. We note that while commenters expressed concerns regarding the potential burden, no one commented on our estimates related to the burden. We believe this indicates that we were accurate in predicting the potential burden associated with this provision.

Therefore, in this final rule, we did not revise the estimates based on comments received, but revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) 2017-2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated service determination request data was not utilized to revise this burden estimate since the data does not impact documenting and tracking the provision of services. Based on the updated data, we have revised the first year burden estimate for this provision which resulted in an increase of 200 hours (from 13,100 hr to 13,300 hr) and $82,532 (from $666,790 to $749,322) from the proposed rule. We have also revised the ongoing burden estimate for this provision which resulted in an increase of 100 hours (from 6,550 hr to 6,650 hr) and $41,266 (from $333,395 to $374,661) from the proposed rule.

d. ICRs Regarding Documentation in Medical Records under PACE (§ 460.210)

Subsequent to the publication of our proposed rule and based on public comment, this final rule revises the proposed requirements in § 460.210(b)(6) to require PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following: (i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both and (ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

Section 460.210 currently sets out the requirements relating to medical records for PACE participants. This includes the minimum content of participant medical records. Under § 460.210(b) of this final rule, CMS requires PACE organizations to maintain additional information and documentation in the medical record, including documentation of all recommendations for services made by employees or contractors of the PACE organization, the

reasons for not approving or providing any service recommended by an employee or contractor of the PACE organization, and original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant.

We expect that PACE organizations will have to revise their policies and procedures and re-train staff on the new requirements. We believe that a compliance officer (quality improvement coordinator) will be responsible for ensuring the necessary materials are updated and that staff are trained. For revising materials and training staff, we estimate a one-time burden of 10 hours at $70.06/hr for a compliance office (quality improvement coordinator) to revise materials and lead training. Therefore, the one-time burden to implement this provision is 1,330 hours (133 PACE organizations * 10 hr) at a cost of $93,180 (1,330 hr * $70.06/hr).

We also estimate this provision will result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about medical record documentation. These assumptions are based on our monitoring and oversight experience.

Each of the new requirements discussed above may require the involvement of any IDT occupation. Therefore, to determine the cost associated with this provision, we took the wages for the full IDT ($846.48/hr) and divided it by the 11 occupations included in the IDT (see Table H15) to determine an average wage of $76.95/hr ($846.48/hr / 11 occupations). We believe this is the most accurate estimate as it will be unlikely all occupations will be working on the medical record at the same time, and we are unable to estimate how much any one occupation will work in comparison to the other occupations.

In the proposed rule, we estimated that the proposed requirement to maintain original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, would not create a significant burden, as organizations would only be required to store existing documentation within a medical record. Therefore, we

estimated that the burden for this part of the provision would be 5 hours per PACE organization or 665 total hours (5 hr * 133 organizations) at a cost of $51,172 (665 hr * $76.95/hr).

Following publication of the proposed rule, while we did not receive any comments specific to our burden estimates for this requirement, we did receive general comments that expressed concern regarding the potential burden associated with storing written communications in a participant's medical record. Based on these comments, we believe we underestimated the burden for this provision. In response to comments received we revised the requirements at § 460.210(b)(6) to permit PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant. This change means that PACE organizations would be required to maintain all covered written communications in § 460.210(b)(6)(i) and (ii), but that they can be maintained in either their original form or as an unaltered electronic copy. In addition to revising the regulatory text to permit PACE organizations to maintain unaltered electronic copies of affected written communications, we are also revising our burden estimates for § 460.210(b)(6). In this final rule, we estimate that the burden for maintaining original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant will be 10 hours per PACE organization or 1,330 total hours (10 hr * 133 organizations) at a cost of $102,344 (1,330 hr * $76.95/hr). This burden is an ongoing burden in all years.

This final rule at § 460.210 also requires a PACE organization to document all recommendations for services from employees or contractors of the PACE organization, including specialists, and require PACE organizations to document the reasons a service recommended by an employee or contractor of the PACE organization is not approved or provided We considered several factors when determining the burden associated with these provisions. First, PACE organizations are already required under § 460.104(b)(1) to document

the rationale for not providing services in developing the plan of care; therefore, this provision will only apply to services recommended following the initial development of the plan of care. Second, PACE organizations will only have to document the rationale under § 460.210(b)(5) when the PACE organization does not approve or provide a recommended service, so there will be no additional burden in situations where the PACE organization approves or provides a recommended service. Considering these two factors, we determined that each PACE organization will have to spend approximately 52 hours (approximately 1 hr per week) to implement this part of the regulation. Therefore, we estimate a total of 52 hours per organization per year, or a total of 6,916 hours (52 hr * 133 organizations) at a cost of $532,186 (6,916 hr * $76.95/hr).

We therefore estimate the total ongoing burden of all aspects of this provision at §460.210 to be 8,246 hours (1,330 hr + 6,916 hr) at a cost of $634,530 ($102,344 + $532,186).

TABLE H15: WAGES FOR IDT STAFF MEMBERS

Occupation Title	Occupation Code	Adjusted Wage* ($/hr)
Dietician	29-1031	59.94
Driver (Passenger Vehicle Driver)	53-3058	31.94
Home Care Coordinator (often a RN)	29-1141	74.48
Masters of Social Work	21-1022	57.02
Occupational Therapist	29-1122	82.90
PACE Center Manager (Medical and Health Services Manager)	11-9111	110.74
Personal Care Attendant	31-1120	25.42
Physical Therapist	29-1123	86.70
Primary Care Provider	29-1216	193.70
Recreational Therapist	29-1125	49.16
Registered Nurse	29-1141	74.48
TOTAL		846.48
Average IDT Cost Per Hour (846.48/11 occupations)		76.95

*See section VIII.A. of this final rule for additional wage information.

We received the following comments on the estimated burden resulting from this provision in the proposed rule.

Comment: Commenters expressed concerns that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would increase burden for PACE organizations as well as increase burden on providers that may be responsible for transferring these communications to the medical record. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste communications received via email or text into electronic medical records.

Response: In response to commenters' concerns, we reviewed our initial burden estimate and determined that we had underestimated the burden for maintaining this documentation in its original format within the medical record. We increased the burden estimate in the final rule accordingly. In determining what an appropriate estimate for this provision would be, we considered both that we may have underestimated the original burden in the proposed rule, as well as the additional operational flexibility that we are allowing for in the final rule, as discussed in greater detail in section VI.F. of this final rule. Given these two factors, we estimate that the burden for maintaining original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant will be 10 hours per PACE organization instead of the 5 hours we initially proposed.

In this final rule, we revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) 2017-2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated service determination request data was not utilized to revise this burden estimate since the data does not impact medical record documentation. The estimates were also revised to account for additional burden for the requirements in § 460.210(b)(6). Based on this updated data, we have revised the burden estimate for revising materials and training related to the changes in this provision which resulted in an increase of 20 hours (from 1,310 hr to 1,330 hr) and $1,847 (from $91,333 to $93,180)

from the proposed rule. We have also revised the burden estimate for the ongoing implementation of this provision which resulted in an increase of 910 hours (from 7,336 hr to 8,246 hr) and $75,453 (from $559,077 to $634,530) from the proposed rule.

e. ICRs Regarding PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed above in section VI.G., this final rule amends the participant rights to identify three additional rights, specifically, the participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines, the right to call 1-800-MEDICARE for information and assistance, and the right to receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community. PACE organizations are currently required to provide a copy of the participant rights to participants at the time of enrollment and to post a copy of the rights in the center. Under this rule, PACE organizations will be required to revise the current participant rights to account for the three new requirements and post a copy of the revised document.

We estimate it will take 2 hours at $70.06/hr for a compliance officer (quality improvement coordinator) to update the participant rights information included in the enrollment information and post the new participant rights in the center. In aggregate, we estimate a one-time burden of 266 hr (133 PACE organizations * 2 hr) at a cost of $18,636 (266 hr * $70.06/hr).

We did not receive any comments related to our projected burden estimates for this provision. With the exception of the adjusted number of organizations, we are finalizing the proposed burden without change.

11. ICRs Regarding Stipulated Decisions in Part C (§ 422.562)

In order to permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, we are providing in § 422.562(d) that, for the sole

purpose of applying § 405.1038(c), MA organizations are included in the definition of "contractors" as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators under § 405.1038. We are scoring this impact as negligible for several reasons. The total number of favorable decisions in MA for contract year 2018, the most recent year for which we have complete appeals data, was 578. The number of these overturned denials that were stipulated decisions is not currently quantifiable as it is not data that existing appeals systems are equipped to track, and ALJs do not track this data on their own.

We consulted with OMHA for its opinion on stipulated decisions. OMHA estimated that the number of contractors submitting oral or written statements in an ALJ hearing or attorney adjudicator review was in the single digits as plans typically prefer an alternate, informal approach that removes the claim from the appeals process altogether: requesting that the beneficiary withdraw their appeal and resubmit their claim for payment.

CMS estimates that while this change would positively impact beneficiaries both in receipt of their items or services, and afford beneficiaries due process protections in a formalized stipulated decisions process, the number of beneficiaries that would be affected is minimal. Despite this estimation of negligible impact, we included this change to promote regulatory uniformity in OMHA's approach to stipulated decisions as far as Medicare contractors are concerned. The submission of a written or oral statement seeking a stipulated decision is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the burden for preparing and filing the oral or written statement for use in the appeal is exempt from the requirements of the PRA.

We received no comments on the assumptions related to our proposed provisions. We are finalizing the burden assessment on these provisions without modification.

C. Summary of Information Collection Requirements and Associated Burden Estimates

TABLE H16: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN [1]

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
SNPS (see ICR #1, above)	422.101(f)(3)	Training	0938-1296	273	273	3	819	NA	70.06	57,379	57,379
SNPS (see ICR #1, above)	422.101(f)(3)	MOC submission	0938-1296	273	273	6	1,638	NA	74.48	121,998	121,998
SNPS (see ICR #1, above)	422.101(f)(3)	MOC off cycle revision	0938-1296	11	11	4	44	NA	74.48	3,277	3,277
SNPS (see ICR #1, above)	422.101(f)(3)	MOC resubmission	0938-1296	14	14	3	42	NA	74.48	3,128	3,128
SNPS (see ICR #1, above)	422.101(f)(1)(iv)	Face to Face	0938-1296	734	734	4	2,936	NA	74.48	218,673	218,673
DMP (see ICR #2, above)	423.153	Creating DMP (for those without DMPs)	0938-0964	79	79	320	25,280	NA	119.49	3,020,707	0
DMP (see ICR #2, above)	423.153	Upload Templates (Those without DMP)	0938-0964	79	79	5	395	NA	89.06	35,179	0
DMP (see ICR #2, above)	423.153	Case Management (those without DMPs	0938-0964	79	158	5	790	NA	109.55	86,545	86,545
DMP (see ICR #2, above)	423.153	Sending notices (those without DMPs)	0938-0964	8	8	0.1667	1.3336	NA	56.34	75	75
DMP (see ICR #2, above)	423.153	Report to CMS (Those without DMPs)	0938-0964	79	158	0.0167	2.6386	NA	56.34	149	149
DMP (see ICR #3, above)	423.153(f)(16)	Revise templates (newly identified PARBs)	0938-0964	288	288	1	288	NA	56.34	16,226	0
DMP (see ICR #3, above)	423.153(f)(16)	Case Management (newly identified PARBs)	0938-0964	288	18,268	5	91,340	NA	109.55	10,006,297	10,006,297
DMP (see ICR #3, above)	423.153(f)(16)	Send notices (newly identified PARBs)	0938-0964	288	8,677	0.1667	1,446	NA	56.34	81,468	81,468
DMP (see ICR #3, above)	423.153(f)(16)	Report to CMS (newly identified PARB)	0938-0964	288	18,268	0.0167	305	NA	56.34	17,184	17,184

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
MTMP (see ICR #5, above)	423.153	Targeting ARBs For MTM	0938-1154	288	7,443	0.6667	4,962	NA	120.68	598,814	598,814
MTMP (see ICR #5, above)	423.153	Mailing ARBs CMR	0938-1154	288	7,443	NA	NA	6,848	N/A	6,848	6,848
MTMP (see ICR #5, above)	423.153	Safe Disposal Page in CMR	0938-1154	288	2,386,955	NA	NA	23,870	N/A	23,870	23,870
MTMP (see ICR #5, above)	423.153	Safe Disposal page in TMR	0938-1154	288	937,495	NA	NA	10,266	N/A	10,266	10,266
Education on addiction (see ICR #6, above)	423.128	Create materials	0938-0964	288	288	2	576	NA	120.68	69,512	0
Education on addiction (see ICR #6, above)	423.128	Update systems	0938-0964	288	288	2	576	NA	89.06	51,299	0
Education on addiction (see ICR #6, above)	423.128	Sending notices	0938-0964	288	35,069,933	NA	NA	384,016		384,016	384,016
Fraud & Abuse Pt C (see ICR #7, above)	422.503(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1383	605	605	247	149,435	NA	91.88	13,730,088	0
Fraud & Abuse Pt C (see ICR #7, above)	422.503(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1383	605	605	156	94,380	NA	91.88	NA	8,671,634
Fraud & Abuse Pt D (see ICR #7, above)	423.504(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1262	63	63	247	15,561	NA	91.88	1,429,745	0
Fraud & Abuse Pt D (see ICR #7, above)	423.504(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1262	63	63	156	9,828	NA	91.88	NA	902,997
RTBT (see ICR #8, above)	423.128	Implementing RTBT	0938-0763	288	288	156	44,928	NA	89.06	4,001,288	0
RTBT (see ICR #8, above)	423.128	Policy Development	0938-0763	29	29	40	1,160	NA	188.36	218,498	0
RTBT (see ICR #8, above)	423.128	Update Systems	0938-0763	29	29	40	1,160	NA	89.06	103,310	0
RTBT (see ICR #8, above)	423.128	Program Maintenance	0938-0763	29	348	30	10,440	NA	36.82	384,401	384,401
Pharmacy performance (see ICR #9, above)*	423.514	Pharmacy performance	0938-0992	5,234	5,234	0.5	2,617	NA	92.46	241,968	241,968
PACE (see ICR #10a, above)	460.104(d)(2) and 460.121	Extension notification	0938-0790	133	2,350	1	2,350	NA	57.02	133,997	133,997

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
PACE (see ICR #10a, above)	460.104(d)(2) and 460.121	Update for extension notification	0938-0790	133	133	2	266	NA	70.06	18,636	0
PACE (see ICR #10b, above)	422.122	Update appeal notices	0938-0790	133	133	5	665	NA	70.06	46,590	0
PACE (see ICR #10c, above)	460.98	Develop written materials for tracking	0938-0790	133	133	50	6,650	NA	56.34	374,661	0
PACE (see ICR #10c, above)	460.98	Tracking services	0938-0790	133	133	50	6,650	NA	56.34	374,661	374,661
PACE (see ICR #10d, above)	460.210	Medical record documentation training	0938-0790	133	133	10	1,330	NA	70.06	93,180	0
PACE (see ICR #10d, above)	460.210	Documentation of written communication about care of PACE enrollees	0938-0790	133	133	62	8,246	NA	76.95	634,530	634,530
PACE (see ICR #10e, above)	460.112	Update for patients' rights	0938-0790	133	133	2	266	NA	70.06	18,636	0
Total				6236	38,467,492	Varies	487,373	424,997	Varies	36,617,099	22,964,175

*The reporting requirements data elements, consistent with our standard, will be specified through the standard non-rule PRA process after publication of this final rule.

IX. Regulatory Impact Analysis

A. Statement of Need

The provisions in this final rule implement specific provisions of the BBA of 2018 and the SUPPORT Act. The statutory need for these policies is clear. However, this rule also contains discretionary policies, including enhancements to the Programs of All-Inclusive Care for the Elderly (PACE) requirements, hence we provide economic justification for some of these noteworthy provisions in the following paragraphs.

Based on industry feedback over the course of several years, and our experiences auditing PACE organizations, we proposed to modify certain PACE requirements to enhance stakeholders' understanding of our requirements and reduce administrative burden. Stakeholders have suggested that the existing processes for addressing service determination requests is burdensome for PACE organizations, and can delay participants' access to services. We are finalizing several changes to the PACE regulations to streamline these processes while ensuring that important participant protections remain intact. We estimate these changes will save PACE organizations, as a whole, approximately $16.8 million in the first year, increasing (due to expected increased PACE enrollment), to $21.3 million in ten years.

Summaries of the public comments that are within the scope of the provisions' proposed regulatory impact analyses implemented in this final rule are included in this section with our responses under the appropriate headings.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive

Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 801–808), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This rule is economically significant under Executive Order 12866, as it may result in over $100 million in costs, benefits, or transfers annually. The Office of Information and Regulatory Affairs has designated this rule as a major rule pursuant to the Congressional Review Act, 5 U.S.C. 804(2).

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This final rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $156 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA-PD, and PDP contracts), 55 state Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $110.74 per hour, including fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average

reading speed, we estimate that it will take approximately 19 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore $ 2100 (19 hours x $110.74). Therefore, we estimate that the maximum total cost of reviewing this final rule is $ 4.2 million ($ $2,104 x 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $ 0.4 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

C. Impact on Small Businesses – Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule has several dozen provisions. Although several provisions are technical or codify existing guidance, and therefore are not expected to have economic impact beyond current operating expenses, there are other provisions with paperwork or other costs. These provisions are analyzed in both this section and in section VIII of this final rule. A compact summary of burdens by year and provision are summarized in Tables H16 and I14 of this final rule. Also, where appropriate the cost burdens and cost savings of groups of provisions that are related are

summarized in this section. For example, Table H16 of section VIII of this final rule lists eight paperwork burdens related to PACE organizations which are summarized in Table I7 of this section. Table I7 is then used in Table I9 to give total savings related to PACE organizations, the total savings reflecting all costs and savings of the various provisions whether paperwork or not.

This rule has several affected stakeholders. They include (1) insurance companies, including the five types of Medicare health plans, MA organizations, PDPs, cost plans, PACE organizations, and demonstration projects, (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies, and (3) enrollees. Some descriptive data on these stakeholders are as follows:

• Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for "small size" with 88 percent of pharmacies, those with under 20 employees, considered small.

• Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for "small size," with 75 percent of insurers having under 500 employees meeting the definition of small business.

• Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.

• Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20-500 employees) considered small.

• Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this final rule does not have a significant economic impact on a substantial number of small entities. To defend our position, we first describe at a high level the cash flows related to the Medicare program. We then provide more specific details.

The high-level underlying idea in creating the MA, Medicare cost plan, and MA-PD Medicare health insurance programs, is to allow private insurers to coordinate care, resulting in efficiencies of cost. The high-level underlying idea in creating the non-government-managed Prescription Drug program (PDPs and drug portion of MA-PDs) is to allow beneficiaries to obtain prescription drugs in a competitive market to reduce costs. For MA, MA-PD, and cost plans, enrollees obtain the same original Medicare Part A and B services they would otherwise obtain in the original Medicare program, generally at reduced cost (however, for the small percentage of plans bidding above the benchmark, enrollees pay more, but this percentage of plans is not "significant" as defined by the RFA and as justified below).

The savings achieved by the MA and the MA-PD plans, the amount of reduced cost, can then be used by the private insurers in a variety of ways, including providing supplemental benefits to the required original Part A and Part B Medicare services. Some examples of these supplemental benefits include vision, dental, and hearing; in addition, MA plans may provide supplemental benefits in the form of reductions in cost sharing compared to the Medicare FFS program. The cost for furnishing these supplemental benefits comes from a combination of the Medicare Trust Fund and enrollee premiums.

Part D plans submit bids and are paid by the Medicare Trust Fund for their projected costs in the form of direct premium subsidy and reinsurance. For any enrolled low-income beneficiaries, plans receive and additional low-income premium subsidy and low-income cost sharing subsidy. The national average monthly bid amount, or NAMBA, determines the base premium. A plan's premium is the sum of the base premium and the difference between its bid amount and the NAMBA.

Thus the cost of providing services by these insurers is met by a variety of government funding and in some cases by enrollee premiums.

In order to achieve these goals, the government pays the MA health plans a portion of the funds that would have been paid had plan enrollees remained in original Medicare. These funds are then used to provide additional benefits on behalf of the health plans' enrollees. This unique insurance relationship has several consequences beneficial to all parties: first, the various insurance programs are not expected to suffer burden or losses since the government subsidizes them; second, the government often incurs savings because health plans, by virtue of coordinating care, are furnishing the same services, albeit often at a reduced cost. This lack of expected burden applies to both large and small health plans. As a consequence of this design, the unique MA regulations, such as those in this final rule, are defined so that small entities are not expected to incur additional burden since the cost of complying with any final rule is passed on to the government.

We next examine in detail each of the stakeholders and explain how they can bear cost. (1) For Pharmacies and Drug Stores, NAICS 446110; (2) for Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) for Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) for SNFs, NAICS 623110: Each of these are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs, PFFS, and MSA, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires

that the payment is governed by a mutually agreed upon contract between the provider and the plan. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the coming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA. There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the government. However, the government also pays the plan a "beneficiary rebate" amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost sharing, lower Part B or Part D premiums, or supplemental benefits. (Supplemental benefits may also partially be paid by enrollee premiums if the plan chooses to use premiums or offers optional supplemental benefits that enrollees may elect to purchase.) It would follow that if the provisions of this final rule cause the bid to increase and if the

benchmark remains unchanged or increases by less than the bid does, then the result would be a reduced rebate and possibly fewer supplemental benefits for the health plans' enrollees.

CMS has observed that from year to year MA organizations prefer to reduce their profit margins, rather than substantially change their benefit package. This is due to marketing forces; a plan lowering supplemental benefits even for one year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it is advantageous for the MA Organization to temporarily reduce margins, rather than reduce benefits.

We note that we do not have definitive data on this. That is, we can at most note the way profit margins and supplemental benefits vary from year to year. The thought processes behind the plan are not reported. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.

A second indirect impact arises from effects on the MLR. More specifically, several provisions of this final rule have non-benefit, administrative classification. For example, the RTBT provision is a requirement for plans to utilize or create certain software; the cost of this creation is classified as administrative and hence is entered in the bid as a non-benefit expense. Similarly, the cost of rewards and incentives is being codified at § 422.134(g)(3) as a non-benefit expense in the plan bid. Several other provisions, including those related to models of care, call centers, and marketing standards, represent non-benefit administrative cost. A non-benefit expense contributes to the denominator of the MLR but not the numerator.

If the costs of complying with a particular provision are excessive, then the MLR could be adversely impacted and MLR requirements could possibly not be met. For contract year 2014 and subsequent contract years, MA organizations, Part D sponsors, and cost plans are required to report their MLRs and are subject to financial and other penalties for failure to meet the statutory requirement that they have an MLR of at least 85 percent (§§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the minimum MLR requirement,

including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination.

There are two ways of showing that this burden is not substantial for at least one provision. As noted in section VIII.B.7. of this final rule, the estimated cost of creating and maintaining an RTBT is $ 4.7 million. We explicitly requested stakeholder impact on this specific estimate and received none. The experience of OACT is that for almost all plans, an extra burden of $0.7 million is unlikely to affect the MLR.

Additionally, the RTBT provision addresses multiple possibilities of implementation, some of them significantly less costly than others. Plans, in implementing the RTBT have the following options: (1) whether they want to develop a new portal, or use an existing computer application, (2) whether they want to offer rewards and incentives to their enrollees who log onto the beneficiary RTBT, (3) whether they want to exclude certain clinically appropriate formulary alternatives from the RTBT, and (4) whether they want to include the negotiated price.

By both allowing exclusions from the RTBT and also by not requiring that plans build their own portals, the RTBT cost may be significantly less than $4.7 million.

Based on the previous discussion, we certify that this final rule does not have a significant economic impact on a substantial number of small entities.

D. Anticipated Effects

Some provisions of this final rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section VIII of this final rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts

from section VIII of this final rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table I13 and the discussion afterwards.

1. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

This provision requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under the Part D sponsor's drug management program. We projected a list of approximately 18,000 beneficiaries that met the criteria for this provision between July 2017 and June 2018, but did not meet other criteria for classification as a potential at-risk beneficiary. Under this provision, this population is projected to 1) increase the population of enrollees requiring case management by plan sponsors (see section IX.B.3. of this final rule), and 2) reduce Part D drug cost.

We evaluated their Prescription Drug Event (PDE) data for the same July 2017 and June 2018 period to determine the effects of this provision. After examining the PDE data, we found that these beneficiaries had an average gross drug cost per beneficiary per year of $9,675. Because this amount is high relative to the typical Part D spending and because they do not meet other at-risk criteria, it is likely that many of these beneficiaries have conditions that require expensive specialty medications. These drugs have complex clinical criteria that are difficult to alter through utilization management. Accordingly, and because there is no directly pertinent information available on the potential savings for increased prescription drug management on this segment of the population, we have, based on the actuarial judgment of staff with pharmaceutical experience as well as based on discussions with pharmacists, assumed that 5 percent of their Part D drug cost would be reduced through additional plan management. We

note that the we received no comments on this estimate as a result of its publication in the proposed rule and therefore believe it reasonable. Our estimated fiscal year federal savings rounded to the nearest million are shown in Table I1. Since these drugs would not be purchased as a result of efficient case management, they represent reduction in goods consumed and are true savings to the Medicare Trust Fund.

TABLE I1: ESTIMATED BENEFITS TO THE MEDICARE TRUST FUND OF THE INCLUSION OF ADDITIONAL AT-RISK BENEFICIARIES

	Fiscal Year ($ in millions)										Total 2023-2032 Impact ($ in millions)
Fiscal Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2032
Estimated Impact	5.8	7.7	7.7	7.7	7.7	7.7	7.7	7.7	7.7	7.7	75.4

Table I2 summarizes the aggregate impact of the changes to DMPs. It reflects all the estimates related to DMPs in section IX of this final rule (which incur costs) and the savings due to reduction in drug costs discussed in this Regulatory Impact Analysis.

TABLE I2: SUMMARY OF DMP IMPACTS BY PROVISION (MILLIONS $) *

	1st Year Savings	1st Year Cost	Annual Savings 2nd – 10th Year	Annual Cost 2nd – 10th Year	Total 10-Year Savings	Total 10-Year Cost
Creation of DMPs for those parent organizations without DMPs		3.0				3.0
Case management of PARBs for those parent organizations without DMPs		0.1		0.1		0.9
Case Management of PARBs with history of opioid overdose		10.0		10.0		100.1
Other paperwork		0.2		0.1		1.0
DMP drug savings	5.8		7.7		75.4	
Total					75.4	105.0
Net Impact (Cost) Over 10 Years						29.6

*Minor discrepancies in the above table are due to rounding. Further detail for DMP paperwork costs may be found in Table H16; the DMP drug savings may be obtained from Table I1.

2. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

The SUPPORT Act requires automatic escalation of drug management program appeals to the independent outside entity contracted with the Secretary for review and resolution. We are finalizing our proposal to codify that provision, with a modification to permit plan sponsors up to 24 hours after the expiration of the applicable adjudication timeframe to assemble and forward the administrative case file to the IRE. We do not believe the modification reflected in this final rule impacts our previous estimate. To estimate the impact, we first determined how many Part D sponsors had implemented drug management plans. As of July 9, 2019, we found that 60 Part D sponsors had implemented drug management plans. Next, we estimated of the number of CARA-appeals per 1,000 enrollees and the percentage of plan denials related to CARA. To do this, we contacted nine Part D sponsors and asked how many CARA related appeals they had received from January 1, 2019 through July 31, 2019.

Of those nine, eight plans responded they had have not received any CARA appeals. One Part D sponsor responded to say they had received CARA related appeals. That plan reported a rate of 0.014 CARA related appeals per 1000 enrollees. This accounted for 0.08 percent of plan denials. Since there are about 28,600 appeals per year, therefore there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46 and typically an IRE will take at most 1 hour to review most cases, the total burden is about $4,656.58 (23 cases * $202.46 * 1 hour) which is entered as $0.0 million in the summary table since regulatory accounting standards impose a rounding to the nearest tenth of a million.

3. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

We were unable to determine the overall impact of implementing sections 2008 and 6063 of the SUPPORT Act because we do not have adequate data to support an estimate of the potential costs and savings. While we do have access to estimates of overall Medicare Part D

opioid spending, sections 2008 and 6063 of the SUPPORT ACT are not expected to impact all Part D opioid prescriptions, nor do we expect that they would impact all pharmacies that dispense those medications. For example, section 2008 of the SUPPORT Act requires Part D plan sponsors to report to CMS any payment suspension pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o) of the Act. In addition, section 6063 of the SUPPORT Act requires MA organizations and Part D plan sponsors to report information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by the plan related to inappropriate prescribing of opioids. In both cases, these provisions would directly impact a percentage of all opioid prescriptions written by prescribers and dispensed by pharmacies. While we believe there may be savings generated through actions taken by Part D plan sponsors that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA-PD plans), as well as additional law enforcement actions, we cannot estimate the impact at this time. We welcomed comment and suggestions for data that could be relied upon for this purpose.

We received no comments on the proposed regulatory impact and consequently we are finalizing them without modification.

4. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We are finalizing measure updates, clarifying and codifying policies in this final rule. These changes are routine and are not expected to have an impact on the highest ratings of contracts (that is, overall rating for MA-PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These types of routine changes have historically had very little

or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

We are also clarifying some of the current rules around assigning Quality Bonus Payment (QBP) ratings and codifying the rules around assigning QBP ratings for new contracts under existing parent organizations. We are not finalizing any changes to our current QBP policies, so there will be no impact on the Medicare Trust Fund from these provisions.

5. Permitting a Second, "Preferred," Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

The option for Part D sponsors to offer a second, "preferred" specialty tier has the potential to impact Part D drug costs in at least two ways. First, a Part D sponsor may have additional negotiating power with brand drug manufacturers by offering a preferential tier position relative to the current single specialty tier. Second, Part D sponsors may promote lower-cost biosimilar biological products on a preferred specialty tier. We consider each of these possibilities in the following discussion.

For a Part D sponsor to be able to negotiate better formulary position and lower beneficiary cost sharing for a particular specialty-tier drug, there must be a substantial difference between the cost sharing on the preferred specialty tier and the higher cost-sharing, specialty tier. Because the regulation limits the maximum allowable cost sharing to the range of 25 to 33 percent, Part D sponsors must achieve this difference by lowering the cost sharing on the preferred specialty tier. For example, because of the high cost for specialty-tier drugs and the structure of the Part D benefit, Part D enrollees and prescribers might not significantly alter their behavior in response to a five percent change in coinsurance. A substantial reduction in the cost sharing for preferred specialty tier would necessitate a substantial increase in cost sharing for other tiers to maintain an actuarially equivalent benefit, which may unfavorably change the competitive position of the Part D sponsor's plan offering. In particular, a plan that offers lower

cost sharing on high-cost specialty-tier drugs and higher cost sharing on conventional drugs would risk adverse selection from Part D enrollees.

In addition, allowing tiering exceptions between the preferred specialty tier and the higher cost-sharing, specialty tier creates a risk for the Part D sponsor that may exceed the benefit of being better able to negotiate with respect to brand drugs. A portion of the higher cost-sharing, specialty-tier drugs may be granted exceptions as the clinical criteria for such Part D drugs is complex and can lead to different prescriptions for beneficiaries with similar conditions. These Part D drugs are often more complicated chemically and apply to complex conditions, such as Rheumatoid Arthritis or Multiple Sclerosis. This added complexity requires greater specialized knowledge than a traditional small molecule drug would for denying an exception. This will be known to manufacturers, who will be less inclined to provide additional incentives for the preferred placement given that a significant amount of non-preferred use will limit any market share gains from their enhanced formulary position. Part D sponsors would also face additional liability from the difference in cost sharing between the preferred and the higher cost-sharing, specialty tiers on prescriptions that are granted tiering exceptions. This dynamic serves as a disincentive for Part D sponsors to place specialty-tier-eligible drugs on a non-specialty, non-preferred drug tier under current regulation.

Regarding savings from biosimilar biological products that could be promoted through a preferred specialty tier, some of the same previously discussed issues still apply. For example, Part D sponsors may expect a portion of a non-preferred reference biological product's utilization to be given an exception to the preferred tier for a biosimilar biological product if such biosimilar biological product is not licensed for all of the same indications as the reference biological product. Furthermore, the selection of these products is often largely determined by the behavior of the prescriber rather than the formulary status of the Part D sponsor. If the prescriber prefers the reference biological product, they are more likely to prescribe it rather than the biosimilar biological product, regardless of the formulary position. This is particularly true

for specialty-tier drugs, where the differences in total drug cost and the cost-sharing requirements of the plan are not as extreme as the differences between conventional brand and generic drugs. Finally, it is worth noting that several large Part D sponsors do not currently promote biosimilar biological products. For example, Zarxio®, a biosimilar biological product to Neupogen®, is not included on the formulary for several large Part D plans.

Our conclusion is that the provisions of the final rule to allow Part D sponsors to structure their benefits with a second, "preferred" specialty tier are unlikely to have a material impact on Part D costs. While it is possible that a small savings to the Part D program could result from the enhanced flexibility, particularly for MA-PD plans with greater prescriber integration, broad adoption of a second specialty tier is unlikely. Nevertheless, we believe there are reasons for a second specialty tier. As discussed in more detail in section IV.E. of this final rule, stakeholders requesting this change have posited that it might lead to better rebates on certain Part D drugs and reduced costs for Part D enrollees and CMS. Most importantly, we are currently not aware of any major adverse effects that could result to Part D enrollees by allowing Part D sponsors to structure their benefits with a second, "preferred" specialty tier. For example, concern for undue financial burden on some Part D enrollees has prompted us to retain the current maximum allowable cost sharing (that is, 25/33 percent, as discussed in more detail in section IV.E. of this final rule). Additionally, we solicited comment regarding whether negative consequences to Part D enrollees could result from this proposal. If there were no foreseeable notable harms to Part D enrollees, it would seem reasonable to provide the requested flexibility to Part D sponsors and see if additional benefits do result, while monitoring implementation for adverse effects and responding as necessary.

As discussed in section IV.E. of this final rule, improving Part D enrollee access to needed drugs, including lowering drug costs, are central goals for CMS. While this regulatory impact analysis assesses the potential impact this policy will have on Part D drug costs, we also believe this policy has the potential to impact patient access and lower drug costs more broadly,

by providing further incentives for manufacturers to develop generic drugs and biosimilar and interchangeable biological products. Even if notable savings for the Part D program were not to materialize, individual Part D enrollees might save a great deal on rebated Part D drugs. Or, the policy might result in the benefit of 1) more formulary choices, or 2) more choices at a lower cost than might have otherwise been the case. These, in turn, might lead to positive health outcomes with associated indirect savings to Part D enrollees or the government. We solicited comment on any other unforeseen benefits that might result. And, again, in finalizing this proposal, we will closely monitor for any adverse effects and take any necessary action including warranted changes for future rulemaking.

Comment: Some commenters suggested that CMS should conduct additional research on the impact of specialty tiers on Part D enrollees, generally, before enacting this policy.

Response: In finalizing our proposals to permit Part D sponsors to maintain up to two specialty tiers, we intend to monitor the uptake of the use of a second specialty tier. We are unclear about, generally, what the commenters believe we should research, given the Part D enrollee protections we are finalizing as part of this final rule.

Comment: Some commenters suggested that the specialty tier(s) serve as perverse "reverse insurance," reasoning that the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit.

Some commenters stated that CMS's proposals exacerbate an existing lack of transparency and the impact of misaligned rebate incentives in the Part D program because CMS's proposal provides no incentive or imposes no requirement that the rebates on these high-cost drugs be passed on to Part D enrollees at the point of sale. They suggested that these misaligned incentives lead to inappropriate tier placements as Part D sponsors choose higher negotiated prices in exchange for higher rebates, and may prefer a drug with a higher net cost over a less expensive alternative. These commenters suggested that CMS's proposals, due to this

inappropriate tier placement, could increase costs to Part D enrollees and the government in two ways: first, as Part D enrollees enter catastrophic coverage more quickly; and second, because Part D enrollees could pay more for preferred products, despite a lower coinsurance percentage, because the coinsurance percent is calculated from a higher list price. These commenters also suggested that misaligned rebate incentives in the Part D program will discourage plan use of newer market alternatives.

Response: We disagree with the sentiment that the specialty tier(s) serve as a perverse, "reverse insurance" whereby the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit. We believe this reasoning is flawed because the specialty tier is aligned with the Defined Standard benefit, and the Part D plan bid requirements also necessitate that the benefit structure below the specialty tier also be actuarially equivalent to the Defined Standard benefit. Therefore, the use of specialty-tier eligible drugs has no differential impact on lowering the premiums and cost sharing on non-specialty tiers for the rest of the benefit. Finally, our proposals would not change the role of rebates in the Part D program.

Comment: Relative to the Part D enrollee and governmental impacts of CMS's proposals, some commenters urged CMS to ensure premiums do not go up, and others expressed concern that cost sharing on other (in other words, non-specialty) tiers would increase as Part D sponsors are required to maintain actuarial equivalence. Some commenters suggested that plans will utilize a second specialty tier to shift more risk of financial exposure to Part D enrollees, leading to higher coinsurance for enrollees who use specialty-tier drugs.

Relative to the Part D sponsor impacts of our proposals, some suggested that CMS's proposals would increase costs to Part D sponsors due to increases in administrative burden from tiering exceptions requests. Others disagreed with CMS's assertion that without any specialty tiers, plan costs would increase, and stated that CMS provided no data to suggest that specialty

tier drugs at lower cost sharing could cause increases to premiums or cost sharing for non-specialty tiers.

Some commenters were concerned that CMS's proposals would increase costs to Part D enrollees, the government, and Part D sponsors. These commenters suggested that if the higher cost-sharing, specialty tier were kept at the current specialty tier cost threshold (in other words, 25/33 percent) with no changes (in other words, permitting the higher cost-sharing, specialty tier to have cost sharing greater than 25/33 percent), the Part D sponsor's costs for specialty drugs would increase, leading, in turn, to higher bids, and higher premiums and cost sharing for Part D enrollees.

Response: Substantial reductions in cost sharing below the 25/33 percent maximum for the preferred specialty tier necessitate substantial increases in cost sharing for non-specialty tiers in order to meet actuarial equivalence requirements. Therefore, we recognize that, in order for Part D sponsors to offer competitive plan benefit designs, Part D sponsors may not offer plan benefit designs with cost sharing for the preferred specialty tier far below the 25/33 percent maximum for the higher cost-sharing, specialty tier, and consequently, Part D enrollee savings for drugs on the preferred specialty tier may be limited. However, because § 423.104(d)(2)(iv)(D) maintains the existing 25/33 percent maximum allowable cost sharing for the specialty tiers, Part D enrollees will not pay more for specialty-tier drugs under our proposals than they do now. Therefore, we disagree that our proposals will increase Part D enrollees' cost sharing for specialty-tier drugs.

We do not understand the commenter's assertion that plans will utilize a second specialty tier to shift more risk of financial exposure to Part D enrollees, leading to higher coinsurance for enrollees who use specialty-tier drugs. While this may be the case in the commercial market, which does not, as a matter of policy, establish or maintain either a specialty-tier cost threshold or a maximum allowable cost sharing, and thus, may have incentives to place more drugs on the specialty tier(s), the methodologies to establish an increase the specialty-tier cost threshold that

we are finalizing in this rule will serve to limit the specialty tier(s) to only the highest-cost Part D drugs. We welcome further input on this matter.

Because specialty-tier drugs are playing an increasing role in the prescription drug marketplace, and we have concern about the impact this will have on the Part D program, we believe that the increase in volume of specialty-tier drugs, but not our proposals, could increase costs to the government.

Regarding administrative burden, tiering exceptions are requested at a much lower volume than formulary exception requests and coverage determinations in general. Based on 2019 Part D plan reported data, tiering exceptions accounted for only 10.8 percent of all exception requests received at the coverage determination level, and 5.6 percent of all coverage determination requests. We do not anticipate that our proposals to permit Part D sponsors to maintain up to two specialty tiers will significantly impact this volume.

Although implementation will be delayed until coverage year 2022, we are finalizing as proposed our proposals to permit a second specialty tier, except that we are not finalizing our proposal to specify a specialty tier threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*) which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase “and biological products,” and paragraph (B) will (1) reflect the

possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

6. Service Determination Request Processes under PACE (§§ 460.104 and 460.121)

We have revised the estimated impact from that presented in the proposed rule in the following ways: 1) we adjusted our estimates to account for an increase in wages according to the May 2019 BLS, 2) we included 2019 PACE audit data which was not available at the time these estimates were published in the proposed rule, 3) we updated enrollment data based on 2017-2019 data from the CMS Office of the Actuary (OACT) and 4) we updated PACE organization contract data based on data from the Health Plans Management System (HPMS). Based on these revisions, we continue to estimate that the finalized provisions will result in savings to PACE organizations.

To estimate the savings from the revisions we are finalizing to the service determination request provisions, we rely upon the assumptions described in the next section. These assumptions are based on our experience monitoring PACE organizations' compliance with current service determination request requirements and on data collected during those monitoring efforts.

We estimate that under the current regulation, the aggregate total annual cost to all PACE organizations for processing service determination requests is approximately $33.2 million.

We estimated that cost by using the following assumptions. First, we estimate the wages for each of the 11 Interdisciplinary team (IDT) members in order to better estimate a total cost. The eleven disciplines shown are the minimum disciplines required to compose the IDT under § 460.102(b). The occupation codes and wages used come from the BLS's website. The wage for each discipline includes the mean hourly wage plus 100 percent of the mean hourly wage for overhead and fringe benefits. Table I3 allows us to estimate the mean hourly wage of the IDT as a whole.

TABLE I3: WAGES FOR IDT STAFF MEMBERS

Occupation Title	Occupation Code	Mean Hourly Wage with Overhead and Fringe Benefits ($)
Dietician	29-1031	59.94
Driver	53-3058	31.94
Home Care Coordinator (often an RN)	29-1141	74.48
Masters of Social Work	21-1022	57.02
Occupational Therapist	29-1122	82.90
PACE Center Manager	11-9111	110.74
Personal Care Attendant	31-1120	25.42
Physical Therapist	29-1123	86.70
Primary Care Provider	29-1216	193.70
Recreational Therapist	29-1125	49.16
Registered Nurse	29-1141	74.48
Total		846.48
Wages/hr (Total/11)		76.95

Currently, when processing a service determination request, the IDT must determine the appropriate discipline(s) to conduct a reassessment under § 460.104(d)(2) and is responsible for notifying the participant or designated representative of its decision to approve or deny a request under § 460.104(d)(2)(iii). Based on our experiences monitoring PACE organizations, we estimate that the IDT takes approximately 1 hour to handle these responsibilities for each service determination request (1 x $846.48= $846.48).

Reassessments performed in response to service determination requests are varied and may be done by multiple disciplines. For purposes of this estimate, we assume a registered nurse (RN) and Master's-level social worker (MSW) conduct reassessments, and that the total hours for reassessments equals 1.5 hours per discipline. Therefore, we estimate that reassessments would cost (1.5 x $74.48 = $111.72) and (1.5 x $57.02= $85.53). This is summarized in Table I4.

TABLE I4: COST PER SERVICE DETERTMINATION REQUEST FOR A PACE ORGANIZATION ASSESSMENT

Occupation Title	Occupation Code	Wage/hr ($)	Time (hr)	Total Cost ($)
Masters of Social Work	21-1022	57.02	1.5	85.53
Registered Nurse	29-1141	74.48	1.5	111.72
Total Cost				197.25

Additionally, once a decision has been rendered, one discipline (usually the MSW) notifies the applicable parties which we believe takes about 1 hour (1 x $57.02 = $57.02). This

is summarized in Table I5.

TABLE I5: COST PER SERVICE DETERMINATION REQUEST FOR A PACE ORGANIZATION NOTIFICATION

Occupation Title	Occupation Code	Wage/hr ($)	Time (hr)	Total Cost ($)
Masters of Social Work	21-1022	57.02	1	57.02

Therefore, the processing of a service determination request under current regulations is $1,100.75 ($57.02 + $846.48 + $197.25) per request.

Additionally, based on combined audit data collected from all PACE organizations in 2017, 2018, and 2019 we estimate there are 705.0 service determination requests per 1000 enrollees (30,173 total service determination requests for 2017, 2018, and 2019 divided by 42,800, the average enrollment for that time period). Consequently, the total cost of processing service determination requests for 2017-2019 under the current regulations was approximately $33.2 million (705.0 service determination requests/1000 enrollees x 42,800 enrollees x $1,100.75 per service determination request) per year.

We anticipate the changes in § 460.121 of this final rule will reduce burden on PACE organizations in the following ways. First, the final rule establishes a streamlined approval process for service determination requests when an IDT member can approve the request in full at the time the request is made, under new § 460.121(e)(2). These approved requests will not need to be brought to the full IDT for review and will not require the IDT to conduct a reassessment. We also do not anticipate notification of the approval adding an additional burden because the IDT member would approve the request immediately and presumably satisfy the notification requirements under § 460.121(j)(1) at the time the request is made. As discussed in section VIII.B.10. of this final rule, we estimate:

- 22.47 percent of all service determination requests are denied, while 77.53 percent are approved; and
- Of the 77.53 percent of service determination requests that are approved, 50 percent of

those are routine (that is, can be approved in full by an IDT member), while 50 percent are not routine.

Consequently,

• 273 service determination requests / 1000 enrollees are routine and approved (50 percent routine x 77.5 percent approved x 705.0 service determination requests/1000 enrollees);

• 158 service determination requests / 1000 enrollees are denied (22.5 percent x 705.0 service determination requests/1000 enrollees); and

• 273 service determination requests / 1000 enrollees are approved but not routine (77.5 percent approved x 50 percent not routine x 705.0 service determination requests / 1000 enrollees).

These estimates are summarized in Table I6.

TABLE I6: BREAKOUT OF SERVICE DETERMINATION REQUESTS BY TYPE

Row ID	Formula	Item	Number or Percentage
(1)		Average enrollment PACE, 2017,2018, 2019	42,800
(2)		Total unduplicated service determination requests (SDR) 2017 – 2019	30,173
(3)	(2) / (1)*1000	Number of SDR per 1000 enrollees	705.0
(4)		Percentage of SDR Approved	77.53%
(5)	100% - (4)	Percentage of SDR with denial	22.47%
(6)		Percentage of approved SDR, easily approved	50%
(7)	(3) * (4)	Total approved SDR per 1000 enrollees	547
(8)	(3) * (5)	Total SR with denial per 1000 enrollees	158
(9)	(7) * (6)	Total easily approved SDR per 1000 enrollees	273
(10)	(7) - (9)	Total not-easily approved SDR per 1000 enrollees	273
(11)	(8)+(9)+(10)	Aggregate SDR per 1000 enrollees per year	705.0

We are finalizing the relevant PACE service determination request proposals without substantive modification, and our burden estimates for the final provisions are based on the following assumptions:

• Service determination requests that an IDT member is able to approve in full at the time the request is made under § 460.121(e)(2) will not require full IDT review, assessment, or a separate notification. Although some work is involved in such approvals, we are estimating the cost as $0 since: i) no reassessment is needed consistent with § 460.121(e)(2)(ii), ii) no separate

notification will generally be needed under § 460.121(j)(1), iii) review by the full IDT is not required under § 460.121(e)(2)(ii) and iv) the estimated time for an IDT member to approve an easily approved service determination request in full is small and hence the total cost is negligible and can be done as a part of the PACE organization's routine day to day activities.

• Denied service determination requests require review by the full IDT under § 460.121(f), an in-person assessment pursuant to 460.121(h)(1), and notification.

• Service determination requests that are approved, but cannot be approved in full at the time the request is made, will require review by the full IDT under § 460.121(f) and notification pursuant to § 460.121(j)(1) but would not require an assessment.

In section VIII.B. of this final rule, we identified eight requirements across five provisions anticipated to increase burden for PACE organizations. These eight requirements, their projected first year costs, and their projected annual costs after the first year are summarized in Table I7.

TABLE I7: PAPERWORK COSTS ASSOCIATED WITH THIS FINAL RULE

Item	1st Year cost*	Cost for years 2-10 if applicable
Extension notification	133,997	133,997
Update for extension notification	18,636	-
Update Appeal Notices	46,590	
Develop written materials for tracking	374,661	
Tracking services	374,661	374,661
Medical record documentation training	93,180	-
Medical record documentation	634,530	634,530
Update for patients' rights	18,636	-
Totals (in Millions $)	1.7	1.1

To estimate the total savings over 10 years we proceed as follows:

• We estimate the total savings without additional paperwork for 2017-2019 by subtracting the projected cost under the proposed provisions from the actual cost under the

current provisions. Table I8 presents these calculations, showing a $15.2 million savings, without considering paperwork, for 2017-2019.

• For any year between 2022 and 2031, we divide the projected enrollment for that year by the actual enrollment for 2017-2019. Since costs are per 1000 enrollees, this quotient when multiplied by 15.2 million will give the savings for that year without considering paperwork requests.

• Finally, since paperwork requests are an additional burden, we subtract paperwork costs from the savings to ascertain the projected savings for that year. In subtracting paperwork costs, we must subtract an annual cost in all years and a special one-time first year cost in 2022. Table I9 presents this 10-year projection.

We illustrate these calculations by deriving the $15.2 million savings estimated based upon the data 2017 through 2019, and presented in Table I9. That is, if the provisions of this rule had been adopted between 2017 and 2019, there would have been a savings of $15.2 million. This can be shown as follows:

• Actual Cost (without paperwork) for 2017-2019: 33.2 million

• Cost (without paperwork) if these provisions were adopted: 18.0 million

• Total savings (Difference of the last two rows): 15.2 million

As we explained previously, in order to arrive at the 33.2 million and the 18.0 million, we considered the following:

• $33.2 = 42,800 enrollees * 705.0 service determination requests/1000 enrollees * $1,100.75 (IDT + assessment + notification)

• $18.0 = $10.6 (10.56) + $7.5 (7.44) + $0

• $10.6 = 42,800 enrollees * 273 service determination requests/1000 enrollees x ($1,100.75-$197.25)

• $7.4 = 42,800 enrollees * 158 service determination requests/1000 enrollees x ($1,100.75)

- $0 = 42,800 enrollees * 273 service determination requests/1000 enrollees x $0

As can be seen, the savings comes from the fact that whereas current regulations require that all 705.0 service determination requests/1000 enrollees be processed by the IDT (at a cost of $1,100.75), the draft final regulations only require that 431 service determination requests (158 service determination requests/1000 enrollees that are denied and 273 service determination requests/1000 enrollees that are approved but not routine) would go to the full IDT for processing, but another 273 service determination requests would be approved and routine and therefore would not impose any administrative cost on the PACE organization. Additionally, the 273 approved but not routine requests that would go to the IDT would be a reduced cost of $1,100.75 - $197.25 since assessments would not be done for all of those approvals. We anticipate this final rule will reduce administrative burden on the PACE organization, and allow IDT members to focus more time on providing participant care.

TABLE I8: ITEMIZED AND TOTAL COST PER YEAR FOR CURRENT OPERATIONS AND PROPOSED FOR BASE PERIOD (2017-2019)

Item	Current	Proposed	Proposed	Proposed	Proposed
	Aggregate SR	Total SR Easily Approved	Total SR Not Easily Approved	Total SR with Denial	Total Cost (millions $) Proposed
Aggregate SR per 1000 per Year	705.0	273	273	158	
Full IDT Review	$846.48		$846.48	$846.48	
Assessment	$197.25			$197.25	
Notification	$57.02		$57.02	$57.02	
Total Cost/SR without Paperwork	$1,100.75	$0.00	$903.50	$1,100.75	
Average Enrollment 2017-2019	42,800	40,151	42,800	42,800	
Total Cost (millions) (2017-2019)	$33.2	$0.0	$10.6	$7.5	18.0
Total Savings (2017-2019) without Paperwork					15.2

TABLE I9: 10-YEAR AGGREGATE PROJECTED SAVINGS FROM PROPOSED PACE PROVISIONS

Year	Enrollment	Base Year Enrollment	Annual Savings 2017 - 2019 without Paperwork	Annual Paperwork Cost	Special 1st Year Paperwork Cost	Adjusted Savings Current Year
(1)	(2)	(3)	(4)	(5)	(6)	(2)/(3)*(4)-((5)+(6))
2022	52,181	42,800	$15.2	1.1	0.6	16.8
2023	53,558	42,800	$15.2	1.1	0	17.9
2024	54,909	42,800	$15.2	1.1	0	18.3
2025	56,259	42,800	$15.2	1.1	0	18.8
2026	57,581	42,800	$15.2	1.1	0	19.3
2027	58,854	42,800	$15.2	1.1	0	19.7
2028	60,069	42,800	$15.2	1.1	0	20.2
2029	61,207	42,800	$15.2	1.1	0	20.6
2030	62,239	42,800	$15.2	1.1	0	20.9
2031	63,195	42,800	$15.2	1.1	0	21.3
Total						193.8

To clarify Table I9, consider the following:

- As noted previously, the actual non-paper savings for the base year, had this provision been implemented between 2017 and 2019, would have been $15.2 million for the 42,800 enrollees.

- The OACT projects 52,181 PACE enrollees for 2022.

- Since enrollment is projected to increase by a factor of 1.2191 (52,181/42,800), and we are estimating service determination requests per 1000 enrollees, we project the non-paper savings for 2022 to be 1.2191 x $15.2 = $18.5 million. In other words, the 2017-2019 costs under the current regulation and proposed regulation would involve a product of 2017-2019 enrollment (about 42,800) times the number of service requests per 1000. The 2022 costs use the same formula, however the 42,800 is replaced by 52,181. It follows that multiplying the 2017-

2019 savings by 52,181/42,800 gives us the correct 2022 savings. Since the difference between the current cost and the proposed cost is savings, it follows that multiplying this difference by the ratio of 52,181/42,800 gives the updated savings).

- However, these are savings without paperwork costs. Table I7 indicates an ongoing $1.1 million cost in all years. . The extra cost in the first year $0.6 million (in addition to the $1.1 ongoing cost) is derived from Table I7 as the total first year cost of $1.7 million minus the ongoing cost in subsequent years of $1.1 million.
- Therefore, the total savings for 2022 would be $18.5 - (1.1 + 0.6) = $16.8 million.
- The other rows are calculated similarly.

Accordingly, the finalized provisions streamline the processes for addressing service determination requests in PACE are projected to save PACE organizations $16.8 million in 2022 with a gradual increase in savings to $21.5 million by 2031. The aggregate savings from 2022-2031 is $193.8 million. These savings are to industry (PACE organizations) because administrative burden is being reduced. Additionally, each blank cell in Table I8 corresponds to a proposal to eliminate an unnecessary burden.

We received no comments regarding the impact related to the proposed PACE provisions however we have revised our estimate in the following ways: 1) we updated our projected costs for §§ 460.121, 460.122, 460.124, 460.98, 460.210, and 460.112 , 2) we adjusted estimates to account for an increase in wages according to the May 2019 BLS, 3) we included 2019 PACE audit data which was not available at the time these estimates were published in the proposed rule, 4) we updated enrollment data based on data from OACT and 5) we updated PACE organization contract data based on data from HPMS.

Specifically, the projected costs for documenting and tracking the provision of services under PACE (§ 460.98), appeals requirements under PACE (§ 460.122), and participant rights (§ 460.112) provisions were updated to account for: 1) an increase in wages according to the May 2019 BLS, 2) updated enrollment data from OACT, and 3) updated PACE organization contract

data based on data from HPMS. Projected costs and savings associated with service determination request (§ 460.121) were updated to account for: 1) an increase in wages according to the May 2019 BLS, 2) updated enrollment data based on data from OACT, 3) updated PACE organization contract data based data from HPMS, and 4) updated service determination request data from PACE audits conducted from 2017 through 2019. As a result of comments, we also revised costs for documentation in medical records under PACE (§ 460.210), which accounts for: 1) an increase in wages according to the May 2019 BLS, 2) updated enrollment data based on data from OACT, 3) updated PACE organization contract data based on data from HPMS, and 4) revisions to the proposed requirements for maintaining all written communications received from a participant or other parties in their original form, as discussed in section VIII.B.10. of this final rule.

7. Beneficiaries with Sickle Cell Disease (§ 423.100)

Based on analysis of 2018 data, we found that about 683 beneficiaries (1.3 percent) who met the minimum OMS criteria or who had a history of an opioid-related overdose had sickle cell disease and would be affected by the finalized exemption. Since we estimate that less than 10 percent of these 683 beneficiaries would have been targeted for case management, the resulting savings is $0.0 million (10 percent x 683 enrollees x $542.46 for each case management).

E. Alternatives Considered

CMS did not develop Alternatives Considered sections for most of the provisions in this final rule as they generally are direct implementations of federal laws or codifications of existing policy for the Part C and D programs. In this section, CMS includes discussions of Alternatives Considered for the provisions to which they are applicable.

1. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

As the Medicare Part D program is a prescription drug benefit and opioid-related overdoses can be due to both prescription opioids, which may be covered under Part D, and illicit opioids, this raises a question of how CMS should define history of opioid-related overdose. CMS considered two options for defining history of an opioid-related overdose plus two alternatives.

Opioid overdose codes (ICD-10) were identified using Medicare FFS Claims data and Part C Encounter data. When considering overdose, we noted that prescription opioids can also be obtained through illegal or illicit means. The available overdose diagnosis codes describe the type of drug involved in the poisoning but do not specify how the drugs were obtained. There is also an unspecified opioid overdose code. Therefore, assumptions were made to classify an overdose code as prescription or illicit. For example, code 40.4 (other synthetic opioids) was classified as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. Conversely, code 40.2 (other opioids) may include poisoning due to oxycodone which was classified as prescription opioid overdose but may have been obtained illegally.

Option 1. Include beneficiaries with either prescription or illicit opioid-related overdoses. This option would allow CMS to proactively identify the most potential at-risk beneficiaries with a history of opioid-related overdoses, regardless whether the opioid is prescription or illicit, so that they can be reported to the Part D sponsor and reviewed through a DMP. This option represents the largest program size of all of the options. Based on data between July 2017 and June 2018, CMS estimates that there were about 28,891 beneficiaries with prescription or illicit opioid-related overdoses who would have been identified and reported as potential at-risk beneficiaries through the OMS.

Option 2: The program size for this option, as a subset of Option 1, decreases by 37 percent to 18,268 if we were to identify only those beneficiaries reported to have at least one opioid prescription drug claim during the 6-month OMS measurement period (approximately 63

percent had opioid Part D claim(s)), which means that they have at least one relatively current opioid prescriber.

Option 3: Identify beneficiaries with only prescription opioid-related overdoses. This approach would utilize a 12-month lookback period to identify beneficiaries with a history of prescription opioid overdoses. Based on data between July 2017 and June 2018, CMS estimates that there were about 21,037 beneficiaries with prescription opioid-related overdoses who would be identified and reported by OMS.

Option 4: Since about 72 percent of beneficiaries had at least one Part D opioid claim in the 6-month OMS measurement period, this option, as a subset of Option 3, decreases the program size to 15,217 beneficiaries if we were to require beneficiaries reported to have at least one opioid prescription drug claim, which means that they have at least one relatively current opioid prescriber.

As noted, the primary impact will result from needing to case manage the additional beneficiaries identified as meeting the proposed definition. At the proposed hour and skill levels defined, this introduces a projected cost of $547.74 per additional beneficiary undergoing case management. The various economic impacts for the alternatives considered are summarized in Table I10.

TABLE I10: ECONOMIC IMPACT OF ALTERNATIVES CONSIDERED

Alternative (Criteria)	Number of Enrollees Affected	Total Cost (millions $)
Option 1	28,891	15.8
Option 2 (finalized)	18,268	10.0
Option 3	21,037	11.5
Option 4	15,217	8.3

CMS is finalizing the proposal to define history of opioid-related overdose as defined in Option 2. This option incorporates the risk factor most predictive for another overdose or suicide-related event and is commensurate with the Administration's commitment to vigorously address the opioid epidemic. However, this approach keeps a clear tie between opioid-related

overdoses and the Part D program by requiring a recent prescription opioid prescriber, which simultaneously increases the likelihood for successful provider outreach through case management by the sponsor. We received no comments on this proposal and therefore are finalizing this provision without modification.

2. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We initially contemplated requiring that each plan as part of its MTM program develop educational materials regarding the safe disposal of prescription drugs that are controlled substances for its beneficiaries. Though each plan would have had a greater cost to develop such materials, the information might have included more local resources specific to individual plans. However, for the sake of consistency, and to reduce burden on MTM programs, we proposed that Part D plans would be required to furnish materials in their MTM programs that meet criteria specified in § 422.111(j) as part of a CMR, TMR, or other MTM correspondence or service.

We also considered whether we should extend MTM eligibility to potential at-risk beneficiaries (PARBs) instead of to just those determined to be at risk. We believe that providing MTM to PARBs might have been beneficial for this population. However, the SUPPORT Act is clear that the extended MTM eligibility criteria should apply only to at-risk beneficiaries.

After careful consideration of all comments received, and for the reasons set forth in section III.E. of this final rule, we are finalizing our proposal to add a requirement that Part D sponsors target ARBs for enrollment in their MTM programs. Part D plan sponsors will be required to comply with this new requirement by January 1, 2022. We are also finalizing the requirement that plans furnish information on safe disposal of prescription drugs that are controlled substances to MTM program enrollees at § 423.153(d)(1)(vii)(E), with a modification to clarify that plans may do so through use of a CMR, TMR or other MTM correspondence or service. We did not receive any comments on our impact analysis.

3. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The provision regarding educating MA and Part D beneficiaries on opioid risks and alternative treatments is discussed in section III.D. of this final rule. In section IX.B.6. of this final rule, we estimated a maximum impact assuming that all plans would want to send all Part D enrollees information and that 75 percent of enrollees would request paper versus electronic communication.

However, we emphasize that the SUPPORT Act does not require CMS to set a standard as to which enrollees receive the required information. As indicated in section III.D. of this final rule, the SUPPORT Act gives plans flexibility to choose which enrollees to send the information. To facilitate plan choice, we have provided a wide range of alternatives in Table I11 The alternatives are based on the number of days the enrollee has been on opioids, the possible gaps in opioid treatment, as well as the cause of the opioid treatment; we, for example, think it very reasonable that sponsors would not want to send notices to opioid users in hospice or with cancer as this could unduly alarm them; therefore, one alternative is to carve these populations out. Although not a policy alternative, we also consider two alternatives for paper estimates; a conservative approach is that only half (50 percent) of enrollees would request paper while the more aggressive approach assumes 75 percent so request. As can be seen, despite the wide range of differences, costs vary only between $0.1 and $0.5 million.

TABLE I11: IMPACTS OF SEVERAL ALTERNATIVES FOR PROVIDING INFORMATION TO OPIOID USERS

(A) Issue	(B) Number of Opioid Users in this Category	(C) Number of Part D Sponsors	(D) Percentage of Enrollees Wanting Paper Delivery	(E) Cost per Plan or Enrollee for Paper Copies	(F) Aggregate Cost (B)* (D)*(E)	(G) Total Cost for this Scenario	Total Cost Rounded (millions)
2 hours of programming	N/A	288	N/A	178.12	51,299	N/A	N/A
2 hours for a pharmacist to develop the materials	N/A	288	N/A	241.36	69,512	N/A	N/A
Total first year programming and development cost	N/A	N/A	N/A	N/A	120,811	N/A	N/A
75% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	75%	0.01095	22,158	142,969	0.1
50% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	50%	0.01095	14,772	135,533	0.1
75% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	75%	0.01095	31,345	152,156	0.2
50% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	50%	0.01095	20,897	141,708	0.1
75% want paper; 7-day usage	7,163,615	N/A	75%	0.01095	58,831	179,642	0.2
50% want paper; 7-day usage	7,163,615	N/A	50%	0.01095	39,221	160,032	0.2
75% want paper; All opioid users (1 year)	11,027,271	N/A	75%	0.01095	90,561	211,372	0.2
50% want paper; All opioid users (1 year)	11,027,271	N/A	50%	0.01095	60,374	181,185	0.2
75% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	75%	0.01095	132,501	253,312	0.3
50% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	50%	0.01095	88,334	209,145	0.2
75% want paper; All Part D enrollees	46,759,911	N/A	75%	0.01095	384,016	504,827	0.5
50% want paper; All Part D enrollees	46,759,911	N/A	50%	0.01095	256,011	376,822	0.4

Comment: A few commenters suggested that sponsors send information on opioid alternatives to all Part D beneficiaries.

Response: As noted earlier in this rule, the SUPPORT Act gives plan sponsors flexibility to choose which enrollees to send the information and sponsors have the most accurate beneficiary information and may wish to select a specific subset to send this information to.

We are finalizing this provision with modification. As explained in section A of this final rule, while the statutory requirement begins with coverage year 2021, this regulation will be applicable beginning January 1, 2022 rather than January 1, 2021 as initially proposed. Although implementation will be delayed until coverage year 2022, we are finalizing without modification for our proposal to permit Part D sponsors to send information on opioid alternatives to all beneficiaries, or to a specific subset as determined by the sponsor.

4. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We would allow Part D sponsors to have two specialty tiers, under the existing policy at § 423.578(c)(3)(ii), Part D sponsors would be required to permit tiering exceptions between the two specialty tiers. We also considered permitting Part D sponsors to exempt tiering exceptions between the two specialty tiers, but we are concerned that removing the Part D enrollee protection requiring exceptions between the two specialty tiers could negate benefits that might otherwise have accrued to Part D enrollees under a two specialty-tier policy when there is a therapeutic alternative on the preferred specialty tier that a Part D enrollee is unable to take.

Additionally, although we proposed to codify at § 423.104(d)(2)(iv)(E) the maximum allowable cost sharing under current policy, because we note that the deductible applies to all tiers and it is unclear that we should continue to differentiate the specialty tier from other tiers on the basis of the deductible, we also considered decreasing the maximum permissible cost sharing to the 25 percent Defined Standard coinsurance for Part D plans with decreased or no deductibles. As a result, we would anticipate that Part D sponsors would need to raise cost sharing on non-specialty-tier drugs to maintain actuarial equivalence. If this applies to all plans, then there should be no budget impact, as they must still return to a basic benefit design that is

actuarially equivalent to the Defined Standard benefit, and there will be no adverse selection. Additionally, we do not expect impacts from this proposal to the private sector, as additional specialty tiers already exist in that market. Plans with a high proportion of dual-eligible enrollees are less likely to offer a second specialty tier, because the lower cost sharing would be less impactful for those beneficiaries. As a result, we don't expect material impacts to Medicaid costs.

Finally, although we proposed at § 423.104(d)(2)(iv)(B) to increase the specialty-tier cost threshold for all plan years in which CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding "to" the nearest $10 increment, in order to reestablish the 1 percent outlier threshold, CMS is also considering a change in this methodology such that CMS would always round "up" to the nearest $10 increment. This rounding up methodology would: (a) ensure that the new specialty-tier cost threshold actually meets the 1 percent outlier threshold, and (b) provide more stability to the specialty-tier cost threshold. Although the $780 30-day equivalent ingredient cost we determined to be the specialty-tier cost threshold for this final rule did not require rounding, had we arrived at a 30-day equivalent ingredient cost of, for example, $772, rounding up to $780 30-day equivalent ingredient cost would have an insignificant impact on the number of drugs meeting the specialty-tier cost threshold.

As noted above, because of conflicting forces, we have not estimated a quantitative cost to this provision and acknowledged at most a possible qualitative savings. Similarly, these alternatives would not change costs.

Comment: We did not receive any comments regarding the alternative on which we solicited comment to always round "up" to the nearest $10 increment.

Response: Due to the balance of other comments, we are not finalizing this alternative.

Comment: Some commenters preferred that CMS permit Part D sponsors to impose cost sharing on the higher-cost sharing, specialty tier higher than the current maximum allowable cost sharing of 25/33 percent.

Response: As discussed in section IV.E. of this final rule, we continue to have concerns that permitting Part D sponsors to impose cost sharing on the higher-cost sharing, specialty tier higher than the current maximum allowable cost sharing of 25/33 percent is discriminatory.

Comment: Some commenters preferred CMS's option to permit Part D sponsors to exempt both specialty tiers from tiering exceptions, even between the two tiers.

Response: As discussed in section IV.E. of this final rule, although we believe reasonable arguments can be made with regard to our statutory authority relative to both our proposal and the alternative, we are concerned that the alternative could make the preferred specialty tier vulnerable to tiering exceptions to the non-specialty tiers, which could impede the ability of Part D sponsors to offer actuarially equivalent benefit designs.

Although implementation will be delayed until coverage year 2022, we are finalizing as proposed our proposals to permit a second specialty tier, except we are not finalizing our proposal to specify a specialty tier threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*) which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph

(A) will remove the phrase "and biological products," and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

5. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

We are requiring that each Part D plan adopt a beneficiary RTBT by January 1, 2023. We had considered requiring that this regulatory action occur by January 1, 2021 to coincide with the requirement of a prescriber RTBT and the other regulatory actions in this rule. However, we wanted to ensure that plans had adequate time to focus on implementing the prescriber RTBT by the currently mandated January 1, 2021 deadline.

This option would probably not change the cost impact which, in section H8 of this final rule, was estimated as $4 million for implementation and $0.4 million for policy development and ongoing maintenance. The major driver of change in cost would be changes in wages. We have already updated the 2018 wages in the NPRM to the current 2019 wages. The wages for general operations manager have decreased while the wages for compliance officer have increased. If we assume this continues for next year there would be no change in the $0.4 million estimate. Computer programmer wages are increased by about 3 percent per year which would increase the $4 million implementation cost by about $0.1 million.

We also considered requiring that plans display this information via a third party website or web application. However, since we discovered that plans already have patient portals that provide some of the mandated information, we believe it would be less confusing for beneficiaries to keep this information on the plan portal. In addition, it would be less of a burden on plans for them to put the information on the portals, rather than supply the information to a third party.

Another variation that we considered was to require that Part D sponsors clarify to enrollees that medications listed in the beneficiary RTBT are based on the formulary and that

options may exist outside of the formulary. However, we ultimately decided that this requirement was not necessary, since Part D formularies already provide a robust array of options for Part D enrollees and we believe that Part D sponsors are in the best positon to judge whether such a statement is necessary. As a result, we declined to adopt this requirement.

We received no comments on our estimated impacts and are therefore finalizing it as proposed.

6. Service Determination Request Processes under PACE (§ 460.121)

As we drafted this provision we considered several alternatives.

Alternative 1: First, we considered requiring that requests that can be immediately approved by a member of the IDT would still require a reassessment. We rejected this approach because the IDT member, based on their knowledge of the participant, would know quickly that the services were appropriate and would therefore not need to conduct a reassessment to make that determination.

Alternative 2: Second, we considered continuing to require that all requests that go to the full IDT would require a reassessment even if the service can be approved. We also rejected this approach because we do not believe it would be necessary to require a reassessment if the IDT can approve a service based on their knowledge of the participant.

The alternatives, the finalized approach, as well as the current approach are listed in Table I12 with total 10-year impact over 10 years.

TABLE I12: CURRENT, FINALIZED, AND ALTERNATIVE SAVINGS

Alternative Description	10-Year Savings (millions $)	SDR Type	Require IDT Review?	Require Reassessment?	Require Separate Notification?
Current	0	Easy approval	Yes	Yes	Yes
		Non-easy approval	Yes	Yes	Yes
		Denied	Yes	Yes	Yes
Finalized	193.8	Easy approval			
		Non-easy approval	Yes		Yes
		Denied	Yes	Yes	Yes

Alternative Description	10-Year Savings (millions $)	SDR Type	Require IDT Review?	Require Reassessment?	Require Separate Notification?
Alternative I	162.5	Easy approval		Yes	
IDT member can easily approve but requires a reassessment		Non-easy approval	Yes		Yes
		Denied	Yes	Yes	Yes
Alternative II	162.5	Easy approval			
IDT member cannot easily approve, require a reassessment for all requests that go to the full IDT		Non-easy approval	Yes	Yes	Yes
		Denied	Yes	Yes	Yes

F. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A–4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table I13, we have prepared an accounting statement showing the savings and costs associated with the provisions of this final rule for calendar years 2022 through 2031. Table I13 is based on Tables I14A, I14B, and I14C which lists savings and costs by provision. Table I13 is expressed in millions of dollars with both costs and savings listed as positive numbers; aggregate impact is expressed as a positive number since the aggregate impact is savings. As can be seen, the net annualized savings of this rule is about $2.9 to $3.4 million per year. The net raw savings over 10 years is $36.9 million. Minor seeming discrepancies in totals in Tables I14A, I14B, and I14C reflects use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these savings from various perspectives may be found in Table I14.

TABLE I13: ACCOUNTING TABLE (MILLIONS $)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Savings in 2021 dollars	3.0	3.5	2022-2031	Federal government, MA organizations, and Part D sponsors

Annualized Monetized Savings in 2021 dollars	26.6	26.8	2022-2031	Federal government, MA organizations, and Part D sponsors
Annualized Monetized Cost in 2021 dollars	23.6	23.3	2022-2031	Federal government, MA organizations, and Part D sponsors

* Both savings and costs are expressed as positive numbers. For example, at 7 percent there is an annualized savings of $26.6 million and an annualized cost of $23.6 million, resulting in an annualized net savings of $3.0 million.

The following Table I14 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table I14 is broken into Table I14A (2022 through 2025), Table I14B (2026 through 2029), and Table I14C (2030 through 2031, as well as raw totals). In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs. All numbers are in millions. Tables I14A, I14B, and I14C form the basis for Table I13. The savings in these tables are true savings reflecting reduced consumption of services and goods.

TABLE I14A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2022 THROUGH 2025*

	2022 Savings	2022 Cost	2023 Savings	2023 Cost	2024 Savings	2024 cost	2025 Savings	2025 Cost
Total Savings	22.6		25.6		26.1		26.5	
Total Costs		34.9		21.8		21.8		21.8
Aggregate Total	(12.3)		3.8		4.2		4.7	
MTMP		0.6		0.6		0.6		0.6
SNP MOCS		0.4		0.4		0.4		0.4
PACE Service Determination requests	16.8		17.9		18.3		18.8	
Fraud & Abuse Pt C,D		15.2		9.6		9.6		9.6
Educating at risk enrollees		0.5		0.4		0.4		0.4
RTBT		4.7		0.4		0.4		0.4
Pharmacy Performance Measures		0.2		0.2		0.2		0.2
Creating DMPs for those without them		3.0				0.0		0.0
Other DMP Paperwork		0.2		0.1		0.1		0.1
DMP Case management for PARBs with opioid overdose history		10.0		10.0		10.0		10.0
Case Management for those parent organizations without DMPs		0.1		0.1		0.1		0.1
DMP Drug savings	5.8		7.7		7.7		7.7	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

TABLE I14B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2026 THROUGH 2029*

	2026 Savings	2026 Cost	2027 Savings	2027 Cost	2028 Savings	2028 Cost	2029 Savings	2029 Cost
Total Savings	27.0		27.5		27.9		28.3	

Total Costs		21.8		21.8		21.8		21.8
Aggregate Total	5.2		5.6		6.1		6.5	
MTMP		0.6		0.6		0.6		0.6
SNP MOCS		0.4		0.4		0.4		0.4
PACE Service Determination requests	19.3		19.7		20.2		20.6	
Fraud & Abuse Pt C,D		9.6		9.6		9.6		9.6
Educating at risk enrollees		0.4		0.4		0.4		0.4
RTBT		0.4		0.4		0.4		0.4
Pharmacy Performance Measures		0.2		0.2		0.2		0.2
Creating DMPs for those without them		-		-		-		-
Other DMP Paperwork		0.1		0.1		0.1		0.1
DMP Case management for PARBs with opioid overdose history		10.0		10.0		10.0		10.0
Case Management for those parent organizations without DMPs		0.1		0.1		0.1		0.1
DMP Drug savings	7.7		7.7		7.7		7.7	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

TABLE I14C: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2030 THROUGH 2031 AND RAW TOTALS*

	2030 Savings	2030 Cost	2031 Savings	2031 Costs	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)
Total Savings	28.7		29.0		269.2	
Total Costs		21.8		21.8		231.3
Aggregate Total	6.8		7.2		37.9	
MTMP		0.6		0.6		6.4
SNP MOCS		0.4		0.4		4.0
PACE Service Determination requests	20.9		21.3		193.8	
Fraud & Abuse Pt C,D		9.6		9.6		101.3
Educating at risk enrollees		0.4		0.4		4.0
RTBT		0.4		0.4		8.2
Pharmacy Performance Measures		0.2		0.2		2.4
Creating DMPs for those without them		-		-		3.0
Other DMP Paperwork		0.1		0.1		1.0
DMP Case management for PARBs with opioid overdose history		10.0		10.0		100.1
Case Management for those parent organizations without DMPs		0.1		0.1		0.9
DMP Drug savings	7.7		7.7		75.4	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

The following information supplements Table I14 and also identifies how impacts calculated in section VIII of this final rule affect the calculations of this section and the tables.

• For two provisions, DMP and PACE, this Regulatory Impact Analysis provides tables summarizing a variety of impacts with line items for the paperwork burdens of section VIII of this final rule. Thus the section VIII impacts are reflected both in Table I14 (summary table) and Table I13 (monetized table) as well as in special tables in this section.

• For six provisions (MTMP, RTBT, SNP MOCs, pharmacy performance measures, educating at risk enrollees, and Fraud and Abuse), the only impacts are calculated in section VIII of this final rule. These six provisions have those section VIII impacts listed in Table I14.

We received comments on impacts in certain individual provisions. These comments as well as our responses, including changes to impacts, have been addressed in the appropriate provision sections, with many of these discussions presented in section VIII.D. of this final rule. Additionally, we did not receive any comments on the summary or monetized table per se and are therefore finalizing these numbers as proposed with appropriate adjustments for provisions not included in this first final rule, the updated impacts, and updated wage estimates.

G. Conclusion

As indicated in Table I13, we estimate that this final rule generates annualized cost savings of approximately $3 to $3.5 million (depending on the discount factor used) per year over 2022 through 2031.

As indicated in Table I14, the primary drivers of savings are (1) revisions to the PACE program resulting in greater efficiencies and (2) increased vigilance for at-risk beneficiaries with a consequent reduction in drug costs. These savings are offset by costs from fraud and abuse efforts and a variety of outreach efforts to at-risk beneficiaries.

The net savings are true savings since they reflect reductions in consumption of goods and services. These savings by plans arising from reduction of services and consumptions of

goods are ultimately passed back to the Medicare Trust Fund which reduce the dollar spending needed for plans.

The savings for the federal government are $75.4 million over 10 years, arising exclusively from DMP savings on reduced prescription drug spending. Administrative savings such as those from the PACE provisions may not accrue directly to the Medicare Trust Fund.

H. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule is a deregulatory action under Executive Order 13771. At a 7 percent rate, this rule is estimated to save $3.7 million a year in 2016 dollars over an infinite time horizon.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs-health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405---FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to reads as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.370(a) is amended by --

a. Revising paragraph (1) of the definition of "Credible allegation of fraud"; and

b. Adding the definition for "Fraud hotline tip" in alphabetical order.

The revision and addition read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

3. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e-5, and 300e-9, and 31 U.S.C. 9701.

4. Section 417.496 is added to read as follows:

§ 417.496 Cost plan crosswalk.

(a) *General rules*--(1) *Definition*. Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition*. (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules*. The cost plan must comply with renewal and nonrenewal rules in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal*. A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal*. A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception*. (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and may permit a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to

another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

PART 422—MEDICARE ADVANTAGE PROGRAM

5. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

Section 422.2 is amended by--

a. Revising the definition of "Institutionalized";

b. Adding the definition of "Parent organization" in alphabetical order to read; and

c. Revising the definition of "Special needs individual".

The revisions and addition read as follows:

§ 422.2 Definitions.

* * * * *

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Special needs individual means an MA eligible individual who is institutionalized or institutionalized-equivalent, as those terms are defined in this section, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

* * * * *

6. Section 422.100 is amended by –

a. Revising paragraphs (c)(1) and (2);

b. Redesignating paragraph (d)(2) as paragraph (d)(2)(i);

c. Adding paragraph (d)(2)(ii);

d. Revising paragraph (m)(5)(iii).

The revisions and additions read as follows:

§ 422.100 General requirements.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing.

(B) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare (This specifically includes Medicare Parts A, B, and D).

(d) * * *

(2) * * *

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

* * * * *

(m) * * *

(5) * * *

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

7. Section 422.101 by—

a. Revising paragraphs (f)(1) introductory text and (f)(1)(i) and (iii); and

b. Adding paragraph (f)(1)(iv);

c. Revising paragraph (f)(2) introductory text; and

d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.

* * * * *

(iii) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(iv) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

* * * * *

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1,

2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark.

8. Section 422.102 is amended--

a. In paragraph (a)(4) by removing the phrase "only as a mandatory" and adding in its place the phrase "for Part A and B benefits only as a mandatory"; and

b. Adding paragraphs (a)(5) and (6).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit (reductions or payment of cost sharing for Part D drugs is not permissible as a Part C supplemental benefit).

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the

specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

* * * * *

9. Section 422.111 is amended by--

a. Removing paragraph (b)(12);

b. Redesignating paragraph (h)(1)(i) as paragraph (h)(1)(i)(A);

c. Adding paragraph (h)(1)(i)(B);

d. Adding paragraphs (h)(1)(ii)(A) through (C);

e. Redesignating paragraph (h)(1)(iii) as (h)(1)(iii)(A);

f. Adding paragraph (h)(1)(iii)(B);

g. Adding paragraphs (h)(1)(iv), (j), and (k).

The revisions and additions read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(h) * * *

(1) * * *

(i)(A) * * *

(B) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan, with the following exceptions:

(1) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(2) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(ii) * * *

(A) For coverage beginning on and after January 1, 2022, limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii) (A) * * *

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

* * * * *

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under an MA plan who is furnished an in-home health risk assessment on or after January 1, 2022 For purposes of this paragraph (j), a health risk assessment furnished to an individual who is residing in an institutional setting, such as a nursing facility, that has the primary responsibility for the disposal of unused medications, is not considered an in-home health risk assessment. As part of the in-home health risk assessment, the enrollee must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary of the written information as described at paragraphs (j)(1) through (6) of this section when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(1) Unused medications should be disposed of as soon as possible.

(2) The US Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or other authorized sites. Include a web link to the information available on the DEA website at www.deatakeback.com and the web link to the DEA search engine which enables beneficiaries to identify drug take back sites in their community at the following web address: https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1.

(3) Community take back sites are the preferred method of disposing of unused controlled substances.

(4) The location of two or more drug take back sites that are available in the community where the enrollee resides.

(5) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers. If applicable, the instructions may also include information on the availability of in-home drug deactivation kits in the enrollee's community.

(6) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(1) *Information requirements for the reporting period*. Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals*. Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements*. (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification before the end of each month that follows the month in which a claim was filed.

(5) *Exceptions*. MA organizations are not required to send the explanation of benefits to dual-eligible enrollees.

10. Section 422.134 is revised to read as follows:

§ 422.134 Reward and incentive programs.

(a) *Definitions*. As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s) program, *reward(s) program*, and *R&I program* mean the same thing as rewards and incentives program.

Incentive(s), *R&I*, and *rewards and incentives* mean the same things as reward(s).

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities*. (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(iv) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(v) Be provided with accommodations consistent with the goal of the target activity to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To ensure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (g)(1) of this section and must not design a program based on the achievement of a health status measurement.

(d) *Reward items*. (1) The reward item for a target activity must meet all of the following:

(i) Be offered identically to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, to the enrollee, such as through transfer of ownership or delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of "points" or "tokens" that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements*. An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure*. MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous*. (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally, all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

11. Section 422.162 is amended—

a. By revising paragraphs (b)(3)(iv)(A) and (B); and

b. By adding paragraph (b)(4).

The additions and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS

measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

(4) *Quality bonus payment ratings*. (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

* * * * *

12. Section 422.164 is amended by revising paragraph (g)(1)(iii)(A) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2022, if there is a contract consolidation as described at § 422.162(b)(3), the TMP or audit data are combined for the

consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

* * * * *

13. Section 422.166 is amended--

a. By adding paragraph (d)(2)(vi); and

b. By adding a sentence to the end of paragraph (i)(8).

The additions read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(d) * * *

(2) * * *

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under § 422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on www.medicare.gov. The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous

3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on www.medicare.gov.

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

* * * * *

(i) * * *

(8) * * * Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

* * * * *

14. Section 422.220 is revised to read as follows:

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

15. Section 422.252 is amended by revising the definition of "New MA plan" to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a plan that meets the following:

(1) Offered under a new MA contract.

(2) Offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

* * * * *

16. Section 422.500 is amended in paragraph (b) by adding the definitions of "Fraud hotline tip", "Inappropriate prescribing", and "Substantiated or suspicious activities of fraud, waste, or abuse" in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier--

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

17. Section 422.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, with the exception of a sanction imposed under § 422.752(d) or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 422.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent organization completed the

acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

* * * * *

18. Section 422.503 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) and (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a

provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1- December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5)* * *

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

* * * * *

19. Section 422.504 is amended by revising paragraph (a)(15) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) Through the CMS complaint tracking system, to address and resolve complaints received by CMS against the MA organization.

* * * * *

20. Section 422.530 is added to subpart K to read as follows:

§ 422.530 Plan crosswalks.

(a) *General rules*--(1) *Definition of crosswalk*. A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/nonrenewal rules*. The MA organization must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility*. Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP.

(5) *Types of MA plans*. For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*--(1) *All MA plans*. An MA organization may perform a crosswalk in the following circumstances:

(i) *Renewal*. A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal*. A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE)*. A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR)*. (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer those affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year, consistent with 42 CFR 422.2263 and 423.2263.

(2) *Special needs plans (SNPs)*. In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C-SNPs)*. (A) Renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

(C) Non-renewing C-SNP with a grouping that is transitioning eligible enrollees into a different grouping C-SNP if the new grouping contains at least one condition that the prior C-SNP contained.

(ii) *Institutional SNP*. (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/ Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions*. In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and may permit a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) plan changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries, considering whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. Crosswalks from a network based PFFS plan to a non-network or partial network PFFS plan will not be permitted.

(2) When MA contracts offered by two different MA organizations that share the same parent organization are consolidated such that the separate contracts are consolidated under one

surviving contract, the enrollees from the consolidating contracts may be crosswalked to an MA plan under the surviving contract.

(3) When a renewing D-SNP with a multi-state service area reduces its service area or, in the case of a D-SNP in an MA regional plan contract, nonrenews and creates state-specific local preferred provider organization plans in its place to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D-SNPs, offered under the same parent organization (even if the D-SNPs are offered by two different MA organizations), and for which the enrollees are eligible, as CMS determines is necessary to accommodate changes to the contracts between the state and D-SNP under § 422.107. For this crosswalk exception, CMS will permit enrollees to be moved between different contracts.

(4) When a renewing D-SNP has another new or renewing D-SNP, and the two D-SNPs are offered to different populations, enrollees who are no longer eligible for their current D-SNP may be moved into the other new or renewing D-SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D-SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D-SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For this crosswalk exception, CMS will not permit enrollees to be moved between different contracts.

(5) Renewing C-SNP with a grouping of multiple conditions that is transitioning eligible enrollees into another C-SNP with one of the chronic conditions from that grouping.

(d) *Procedures*. (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An MA organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies

requesting MA organizations of the approval or denial after the crosswalk exception request deadline.

21. Section 422.550 is amended by adding paragraph (f) to read as follows:

§ 422.550 General provisions.

* * * * *

(f) *Sale of beneficiaries not permitted*. (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

22. Section 422.562 is amended by adding paragraph (d)(3) to read as follows:

§ 422.562 General provisions.

* * * * *

(d) * * *

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of "contractors" as it relates to stipulated decisions.

23. Section 422.568 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization dismisses an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a request with the MA organization.

24. Section 422.570 is amended by adding paragraph (g) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization dismisses an expedited organization request in accordance with § 422.568.

25. Section 422.582 is amended—

a. In paragraph (e) by removing the word "written"; and

b. By adding paragraphs (f) through (i).

The additions to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(f) *Dismissing a request.* The MA organization dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

26. Section 422.584 is amended by adding paragraph (g) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(g) *Dismissing a request*. The MA organization dismisses an expedited reconsideration request in accordance with § 422.582(f) through (i).

27. Section 422.590 is amended by adding paragraph (i) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(i) *Requests for review of a dismissal by the independent entity*. If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other proper party under § 422.578 has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

28. Section 422.592 is amended—

a. In paragraph (a) by adding a sentence at the end of the paragraph; and

b. By adding paragraphs (d) through (i).

The additions to read as follows:

§ 422.592 Reconsideration by an independent entity.

(a) * * * In accordance with § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

* * * * *

(d) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a request for withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

29. Section 422.600 is amended in paragraph (b) by adding a new sentence at the end of the paragraph to read as follows:

§ 422.600 Right to a hearing.

* * * * *

(b) * * * For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

* * * * *

30. Section 422.629 is amended by revising paragraph (k)(4)(ii) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(4) * * *

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision.

* * * * *

31. Section 422.631 is amended by adding paragraphs (e) through (i) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(e) *Dismissing a request.* The applicable integrated plan dismisses a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a request with the applicable integrated plan.

32. Section 422.632 is amended in paragraph (b)(1) by removing the reference "§ 422.633(e)" and adding in its place the reference "§ 422.633(d)".

§ 422.632 [Amended]

33. Section 422.633 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan dismisses an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(*l*) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the dismissal is vacated under paragraph (j) of this section.

34. Section 422.760 is amended by redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively, and adding a new paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*--(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty*. The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s)*. Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier*. The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by The Office of Management and Budget (OMB) annually.

(ii) *Calculation of minimum penalty amounts.* (A) Per determination and per enrollee minimum penalty amounts increases by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts is updated no more often than every 3 years.

(C) CMS does the following:

(*1*) Tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts.

(*2*) Announces the penalties and amounts described in paragraph (b) of this section on an annual basis.

* * * * *

35. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the Internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

36. Section 422.2261 is added to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements*. MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization.

(3) Unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms*. MA organizations may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of non-marketing communications materials*. CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review*. CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

37. Section 422.2262 is revised to read as follows:

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules*. MA organizations must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, except when used in logos or taglines.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, “Super Medicare Advantage (HMO).” MA organizations are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment, except for factually accurate descriptions of the MA organization’s policies adopted in accordance with § 422.74(b)(1) and (d)(1) of this chapter.

(xiii) Use the term “free” to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term "Medicare-approved" to describe benefits or services in materials or both.

(iii) Use the term "free" in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials*. (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1-800-MEDICARE or Medicare TTY appears, the MA organization must prominently include, at least once, the hours and days of operation for 1-800-MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, "H" for MA or Section 1876 Cost Plans, "R" for Regional PPO plans (RPPOs), or "Y" for MCE, a means of identification available for Plans/Part D sponsors that have multiple MA contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word "MULTI-PLAN" instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI-PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization’s discretion) unique to the material followed by an underscore.

(iii) An uppercase "C" for communications materials or an uppercase "M" for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

38. Section 422.2263 is added to read as follows:

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that "Other providers are available in the network."

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including

but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the MA organization's website about the existence of OEP.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how MA organizations must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA-PDs and the summary rating for MA-only plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable, unless using Star Ratings to convey overall MA organization performance (for example, "Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the MA organization must do so in a way that is not confusing or misleading

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5-star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5-star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

39. Section 422.2264 is revised to read as follows:

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact*. Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business*. MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) When reaching out to a beneficiary regarding plan business, as outlined in this section, MA organizations must offer the beneficiary the ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries*. MA organizations and their agents or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) MA organizations may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) If a marketing event directly follows an educational event, the beneficiary must be made aware of the change and given the opportunity to leave prior to the marketing event beginning.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, "cherry-picking").

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products, such as annuities.

40. Section 422.2265 is added to read as follows:

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements*. (1) MA organization websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content*. MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A searchable provider directory.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the Medicare.gov electronic complaint form.

(9) Disaster and emergency policy consistent with § 422.100(m)(5)(iii).

(10) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(11) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(12) For MSA plans, the following statements:

(i) "You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty."

(ii) "Tax publications are available on the IRS website at http://www.irs.gov or from 1-800-TAX-FORM (1-800-829-3676)."

(c) *Required posted materials*. MA organization's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

41. Section 422.2266 is added to read as follows:

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities*. Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the "Medicare & You" handbook, or "Medicare Options Compare" (from https://www.medicare.gov), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at https://www.medicare.gov, or 1-800-MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities*. Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities performed on behalf of the MA organization.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting*. MA organization activities in the health care setting are those activities, including marketing activities that are conducted by MA organization staff or on behalf of the MA organization, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

(f) *Activities of Institutional Special Needs Plans (I-SNPs) Serving Long-Term Care Facility Residents* (1) Depending on the context of a given situation, I-SNP contracted with a long-term care facility can be viewed as both a provider and a plan.

(2) I-SNPs may use staff operating in a social worker capacity to provide information, including marketing materials (excluding enrollment forms), to residents of a long term care facility.

(3) Social workers of the I-SNP (whether employees, agents, or contracted providers) may not accept or collect a scope of appointment or enrollment form on behalf of the I-SNP.

(4) Unless the beneficiary or the beneficiary's authorized representative initiates additional contact with or by the plan, all other marketing and outreach activities in the beneficiary's room must follow the requirements for beneficiary contact under § 422.2264

(5) All other activities with healthcare providers or in the healthcare setting must comply with §§ 422.2266(a), (b), (c), (d), and (e).

42. Section 422.2267 is added to read as follows:

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content*. All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials*. Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) The MA organization may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and MA organizations may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials*. Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials*. MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard-copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content*. The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to § 422.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC)*. The EOC is a standardized communications material through which certain required information (under § 422.111(b)) must be provided annually and must be provided:

(i) To current enrollees of the plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB)*. The EOB is a model communications material through which plans must provide the information required under § 422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC)*. The ANOC is a standardized marketing material through which plans must provide the information required under § 422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL)*. The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB)*. MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on medical benefits, including:

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Information on prescription drug expenses, including:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30-or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) A statement that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D-SNP)s, the SB must identify or describe the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document identifying the Medicaid benefits that accompanies the SB.

(E) For D-SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D-SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form*. This is a model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice*. This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice*. This is a model communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare health plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 422.506(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA-PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's' region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1-800-MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy, and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy, options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory.* This is a model communications material through which plans must provide the information under § 422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B)*(1)* Updates to hardcopy provider directories must be completed within 30 days.

(2) Hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice.* This is a model communications material through which plans must provide the information required under § 422.111(e). The provider termination notice must be both of the following:

(i) Provided in hard copy.

(ii) Sent via U.S. mail (first class postage is recommended, but not required).

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organizations that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice*. This is a model communications material through which plans must notify enrollees when a provider they visit or consult has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN))*. This is a standardized communications material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC)*. This is a standardized communications material used to convey beneficiary appeal rights when a plan is terminating previously-approved coverage in a Skilled Nursing Facility (SNF), Comprehensive Outpatient Rehabilitation Facility (CORF), or Home Health setting (HHA).

(18) *Detailed Explanation of Non-Coverage (DENC)*. This is a standardized communications material used to convey to a beneficiary why their current Medicare covered SNF, CORF or HHA services should end.

(19) *Appointment of Representative (AOR)*. This is a standardized communications material used to authorize or appoint an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM)*. This is a standardized communications material used to convey a beneficiary's rights as a hospital inpatient and appeal rights when their covered inpatient hospital stay is ending.

(21) *Detailed Notice of Discharge Form (DND)*. This is a standardized communications material, as required under § 422.622(e), used to convey to a beneficiary why their current Medicare covered inpatient hospital stay should end.

(22) *Medicare Outpatient Observation Notice (MOON)*. This is a standardized communications material used to inform a beneficiary that he or she is an outpatient receiving observation services.

(23) *Appeal and Grievance Data Form*. This is a standardized communications material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing*. This is a standardized communications material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing*. This is a standardized communications material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance*. This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement*. This is a model communications material used by non-contracted providers to waive beneficiary liability for payment for denied services while utilizing the enrollee appeals process under subpart M of part 422.

(28) *Notice of Appeal Status*. This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal*. This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(31) *Star Ratings Disclaimer.* This is model content through which plans must:

(i) Convey that MA organizations are evaluated yearly by Medicare.

(ii) Convey that the ratings are based on a 5-star rating system.

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(32) *SSBCI Disclaimer.* This is model content through which MA organizations must:

(i) Convey the benefits mentioned are a part of special supplemental benefits.

(ii) Convey that not all members will qualify.

(iii) Include the model content in the material copy which mentions SSBCI benefits.

(33) *Accommodations Disclaimer*. This is model content through which MA organizations must:

(i) Convey that accommodations for persons with special needs are available.

(ii) Provide a telephone number and TTY number.

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events described under § 422.2264(c).

(34) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: "Important [Insert Plan Name] information."

(ii) MA organizations must include the following statement when mailing health and wellness information: “Health and wellness or prevention information.”

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(35) *Promotional Give-Away Disclaimer*. This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(36) *Provider Co-branded Material Disclaimer.* This is model content through which MA organizations must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan’s network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned, unless the co-branding is with a provider network or health system that represents 90 percent or more of the network as a whole.

(37) *Out of Network Non-Contracted Provider Disclaimer.* This is standardized content. The disclaimer consists of the statement: “Out-of-network/non-contracted providers are under no obligation to treat Plan members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost-sharing that applies to out-of-network services,” and must be included whenever materials reference out-of-network/non-contracted providers.

(38) *NCQA SNP Approval Statement.* This is model content and must be used by SNPs who have received NCQA approval. MA organizations must:

(i) Convey that MA organization has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP).

(ii) Include the last contract year of NCQA approval.

(iii) Convey that the approval is based on a review of [insert Plan Name's] Model of Care.

(iv) Not include numeric SNP approval scores.

§ 422.2268 [Removed]

43. Section 422.2268 is removed.

44. Section 422.2274 is revised to read as follows:

§ 422.2274 Agent, broker, and other third party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions*. For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA-PD replaced with another MA or MA-PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA-PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA-PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA-PD plan or PDP.

(b) *Agent/broker requirements*. Agents and brokers who represent MA organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight*. MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell, including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in MA plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish

and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements*. MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules*. (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay pro-rated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an "unlike plan type" change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at an amount up to 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new "like plan type".

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA-PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA-PD), the MA organization may only pay compensation at the renewal rate for the MA-PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs)*. (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments)*. (1) Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Administrative payments can be based on enrollment provided payments are at or below the value of those services in the marketplace.

(f) *Payments for referrals*. Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries) to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA-PD plan and $25 for a referral into a PDP plan.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

45. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, and 1395hh.

46. Section 423.4 is amended by adding definitions for "Credible allegation of fraud", "Fraud hotline tip", "Inappropriate prescribing", "Parent organization", and "Substantiated or suspicious activities of fraud, waste, or abuse" in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

* * * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining

inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

* * * * *

47. Section 423.100 is amended—

a. In the definition of "Applicable drug" by revising paragraph (1)(ii);

b. In the definition of "Exempted beneficiary" by:

i. Removing the word "or" at the end of paragraph (2);

ii. Removing the period at the end of paragraph (3) and adding "; or" in its place; and

iii. Adding paragraph (4); and

c. By revising the introductory text in the definition of "Potential at-risk beneficiary".

The revisions and addition read as follows:

§ 423.100 Definitions.

* * * * *

Applicable drug * * *

(1) * * *

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and

* * * * *

Exempted beneficiary * * *

(4) Has sickle cell disease.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual who is not an exempted beneficiary (as defined in this section) and—

* * * * *

48. Section 423.104 is amended by adding paragraph (d)(2)(iv) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iv) Specialty tier means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(*2*) of this section) that are greater than the specialty tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold.* CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(*1*) *30-day equivalent ingredient cost*. Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(*2*) *30-day equivalent supply.* CMS determines the 30-day equivalent supply as follows: if the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(*3*) *Top 1 percent.* CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(*4*) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(*5*) *Claims history.* Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold.

(*6*) *No claims history*. For newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated prices for a 30-day equivalent supply, as defined in subparagraph (d)(2)(iv)(A)(*2*), is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to the requirements at § 423.120(b).

(B) *Limit on specialty-tier cost threshold adjustment.* (*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold.* CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing.* A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(*1*) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(*2*) For Part D plans with no deductible, 33 percent coinsurance.

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D-2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

* * * * *

49. Section 423.128 is amended by—

a. Revising paragraph (a)(1);

b. Adding paragraph (b)(11);

c. Adding paragraphs (d)(1)(i)(A) and (B), and (ii)(A) through (C);

d. Redesignating paragraph (d)(1)(iii) as (d)(1)(iii)(A);

e. Adding paragraph (d)(1)(iii)(B); and

f. Adding paragraphs (d)(1)(v) and (vi) and (d)(4) and (5).

The revisions and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

(a) * * *

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part, except as provided in paragraph (b)(11)(ii) of this section;

* * * * *

(b) * * *

(11) *Opioid information*. (i) Beginning January 1, 2022, and subject to paragraph (b)(11)(ii) of this section, a Part D sponsor must disclose to each enrollee at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications –

(*1*) In the case of an MA-PD, under such plan; and

(*2*) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan, with the following exceptions:

(*1*) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(*2*) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(B) For coverage beginning on and after January 1, 2022, any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) * * *

(A) For coverage beginning on and after January 1, 2022, limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) * * *.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

* * * * *

(v) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

(vi) For coverage beginning on and after January 1, 2022, provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

* * * * *

(4) Beginning on January 1, 2023, a Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Formulary medication alternatives for a given condition.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (vi) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of reasonable value, both individually and in the aggregate.

(ii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, health status, or other prohibited basis.

(iii) Not be offered in the form of cash or other cash equivalents.

(iv) Not be used to target potential enrollees.

(v) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vi) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

* * * * *

50. Section 423.153 is amended by—

a. Revising the section heading;

b. Revsing paragraph (a);;

c. By adding paragraphs (d)(1)(vii)(E) and (F);

d. By revising paragraph (d)(2);

e. By revising paragraph (f)(1) introductory text;

f. In paragraph (f)(3)(ii) introductory text by removing the phrase "paragraphs (f)(10) and (11) of this section" and adding its place the phrase “paragraphs (f)(9) through (13) of this section";

g. In paragraph (f)(4)(ii)(A) by removing the phrase "paragraph (f)(2)(ii)(B) of this section" and adding its place the phrase "paragraph (f)(3)(ii)(A) of this section";

h. In paragraph (f)(4)(ii)(A) by removing the phrase "paragraph (f)(4)(i)(B) of this section" and adding its place the phrase "paragraph (f)(2)(i)(B) of this section";

i. Revising paragraphs (f)(5)(ii)(C)(*3*), (f)(6)(ii)(C)(*4*), and (f)(8)(i);

j. In paragraph (f)(15)(ii)(C) by removing the phrase "any potential at-risk beneficiary" and adding in its place the phrase "any potential at-risk beneficiary or at-risk beneficiary" and changing “definition” to “definitions”;

k. In paragraph (f)(15)(ii)(D) by changing “no later than 7 days of the date” to “no later than 7 days from the date”;

l. By revising paragraph (f)(16); and

m. By revising the heading of paragraph (g).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), drug management programs, and access to Medicare Parts A and B claims data extracts.

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section. No later than January 1, 2022, a Part D plan sponsor must have established a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section.

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(E) Beginning January 1, 2022, for enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or other MTM correspondence or service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

(i)(A) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(C) Are likely to incur the following annual Part D drug costs:

(*1*) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(*2*) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv); or

(ii) Beginning January 1, 2022, are at-risk beneficiaries as defined in § 423.100.

* * * * *

(f) * * *

(1) *Written policies and procedures*. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. In the case of a Part D sponsor, including a PACE organization, without its own or a contracted P&T committee because it does not use a formulary, the written policies and procedures described in this section must be approved by the Part D sponsor's medical director as described at § 423.562(a)(5) (or, for a PACE organization, at § 460.60(b)) and applicable clinical and other staff or contractors as determined appropriate by the medical director. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

* * * * *

(3) * * *

(ii) In accordance with paragraphs (f)(9) through (13) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are –

* * * * *

(4) * * *

(A) Except as provided in paragraph (f)(3)(ii)(A) of this section regarding a prescriber limitation, if the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(2)(i)(B) of this section for eliciting information from the prescribers.

(5) * * *

(ii) * * *

(C) * * *

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at §§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(6) * * *

(ii) * * *

(C) * * *

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(*i*) A description of both the standard and expedited redetermination processes.

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*iii*) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(8) * * *

(i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days

after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) The date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

(15) * * *

(ii) * * *

(C) Provide information to CMS about any potential at-risk beneficiary or at-risk beneficiary that meets paragraph (2) of the definitions in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

(D) Provide information to CMS as soon as possible but no later than 7 days from the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 7 days from a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

* * * * *

(16) *Clinical guidelines*. Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or a Part D sponsor using clinical guidelines that –

(i) Are developed with stakeholder consultation;

(ii) Are based on:

(1) The acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors; or

(2) Beginning January 1, 2022, a history of opioid-related overdose as determined by at least one recent claim that contains a principal diagnosis indicating opioid overdose,

and at least one recent claim for an opioid medication other than an opioid used for medication assisted therapy (MAT).

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts*-- * * *

* * * * *

51. Section 423.182 is amended by revising paragraphs (b)(3)(ii)(A) and (B) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and

surviving contracts for all measures except for CAHPS. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except CAHPS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

52. Section 423.184 is amended by revising paragraph (g)(1)(ii)(A) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2022, if there is a contract consolidation as described at § 423.182(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(ii)(B) through (M) of this section is applied.

* * * * *

53. Section 423.186 is amended by adding a sentence to the end of paragraph (i)(6) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(i) * * *

(6) * * * Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

* * * * *

54. Section 423.265 is amended by revising paragraph (b)(2) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

* * * * *

55. Section 423.286 is amended by revising paragraph (d)(4)(ii) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(d) * * *

(4) * * *

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage – 25.5 percent)/25.5 percent).

* * * * *

56. Section 423.503 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under to subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

* * * * *

57. Section 423.503 is amended by revising paragraph (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

* * * * *

58. Section 423.504 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The Part D plan sponsor must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include

referral information and actions taken by the Part D plan sponsor on the referral. (*6*)(*i*) The plan sponsor is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1- December 31).

(*7*)(*i*) CMS provides plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)*(i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

* * * * *

59. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the MA organization.

* * * * *

60. Section 423.514 is amended by redesignating paragraph (a)(5) as paragraph (a)(6) and adding a new paragraph (a)(5) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) * * *

(5) Pharmacy performance measures.

* * * * *

61. Section 423.551 is amended by revising paragraph (g)(2) to read as follows:

§ 423.551 General provisions.

* * * * *

(g) * * *

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

* * * * *

62. Section 423.560 is amended by—

a. Removing the definition of "Appointed representative";

b. Adding the definition of "Representative" in alphabetical order; and

c. Revising the definition of "Specialty tier".

The addition and revision read as follows:

§ 423.560 Definitions.

* * * * *

Representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M, of this chapter.

Specialty tier: (1) Before January 1, 2022, means a formulary cost-sharing tier dedicated to very high cost Part D drugs that exceed a cost threshold established by the Secretary; and

(2) Beginning January 1, 2022, has the meaning given the term in § 423.104.

63. Section 423.566 is amended by revising paragraph (c)(2) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(c) * * *

(2) The enrollee's representative, on behalf of the enrollee; or

* * * * *

64. Section 423.568 is amended by adding paragraphs (i) through (m) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(i) *Dismissing a request*. The Part D plan sponsor dismisses a coverage determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the individual making the request is not permitted to request a coverage determination under § 423.566(c).

(2) When the Part D plan sponsor determines the party failed to make out a valid request for a coverage determination that substantially complies with paragraph (a) of this section.

(3) When an enrollee or the enrollee's representative files a request for a coverage determination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(4) When a party filing the coverage determination request submits a timely request for withdrawal of the request for a coverage determination with the Part D plan sponsor.

(j) *Notice of dismissal.* The Part D plan must mail or otherwise transmit a written notice of the dismissal of the coverage determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(k) *Vacating a dismissal.* If good cause is established, the Part D plan sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(*l*) *Effect of dismissal.* The Part D plan sponsor's dismissal is binding unless it is modified or reversed by the Part D plan sponsor or vacated under paragraph (k) of this section.

(m) *Withdrawing a request.* A party that requests a coverage determination may withdraw its request at any time before the decision is issued by filing a request with the Part D plan sponsor.

65. Section 423.570 is amended by adding paragraph (f) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited coverage determination in accordance with § 423.568.

66. Section 423.578 is amended—

a. By revising paragraph (a)(6)(iii); and

b. In paragraph (b)(4) by removing the phrase "the enrollee's appointed representative" and adding in its place the phrase "the enrollee's representative".

The revision reads as follows:

§ 423.578 Exceptions process.

(a) * * *

(6) * * *

(iii)(A) Before January 1, 2022, if a Part D plan sponsor maintains a specialty tier, as defined in §423.560, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier are not eligible for a tiering exception.

(B) Beginning January 1, 2022, if a Part D sponsor maintains one or two specialty tiers, as defined in § 423.104, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exception(s) to non-specialty tiers.

* * * * *

67. Section 423.582 is amended—

a. In paragraph (d) by removing the word “written” and

b. By adding paragraphs (e) through (h).

The additions read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(e) *Dismissing a request.* A Part D plan sponsor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee’s representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal*. The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the decision is vacated under paragraph (g) of this section.

68. Section 423.584 is amended by adding paragraph (f) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(f) *Dismissing a request*. The Part D plan sponsor dismisses an expedited redetermination in accordance with § 423.582.

69. Section 423.590 is amended by adding paragraphs (i) and (j) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other proper party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

70. Section 423.600 is amended by—

a. Revising paragraph (b); and

b. Adding paragraphs (f) through (k).

The revision and additions read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

* * * * *

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

* * * * *

(f) The party who files a request for reconsideration may withdraw it by filing a request with the IRE.

(g) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (a) of this section.

(4) When an enrollee or the enrollee’s representative files a request for reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee’s surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee’s representative, if any, does not wish to continue the appeal.

(5) When a party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration consistent with § 423.590. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

71. Section 423.760 is amended by—

a. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and

b. Adding a new paragraph (b)(3).

The addition reads as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessments imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*--(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty*. The per enrollee or per determination amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s)*. Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier*. The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by the Office of Management and Budget (OMB) annually.

(ii) *Calculation of penalty amounts*. (A) Per determination and per enrollee penalty amounts are increased by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts will be updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announce them on an annual basis.

* * * * *

72. Section 423.2006 is amended by redesignating paragraphs (c)(1) and (2) as paragraphs (c)(2) and (3) and adding a new paragraph (c)(1) to read as follows:

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(c) * * *

(1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including

deductible, coinsurance, or copayment amounts that may be collected from the enrollee for the Part D drug(s).

* * * * *

§ 423.2014 [Amended]

73. Section 423.2014 is amended in paragraph (a)(1)(ii) by removing the phrase "appointed representative" and adding in its place the phrase "representative".

§ 423.2036 [Amended]

74. Section 423.2036 is amended in paragraphs (c) and (d) by removing the phrase "appointed representative" and adding in its place the phrase "representative" each time it appears.

75. Section 423.2260 is revised to read as follows:

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the Part D sponsor (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the Internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a Part D plan or plans.

(B) Influence a beneficiary's decision making process when making a Part D plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the Part D sponsor's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

76. Section 423.2261 is added to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements*. Part D sponsors must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor.

(3) Unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms*. Part D sponsors may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS.

(3) The material has been accepted under File and Use, as follows:

(i) The Part D sponsor may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review*. CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

77. Section 423.2262 is revised to read as follows:

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules*. Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements except when used in logos or taglines.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, “Super Medicare Drug Plan (PDP)”. Part D sponsors are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment except for factually accurate descriptions of the PDP sponsor’s policies adopted in accordance with § 423.44(b)(1) and (d)(1) of this chapter.

(xiii) Use the term “free” to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term "Medicare-approved" to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials*. (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1-800-MEDICARE or Medicare TTY appears, the Part D sponsor must prominently include, at least once, the hours and days of operation for 1-800-MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, "S" for PDPs, or "Y" for MCE, a means of identification available for Plans/Part D sponsors that have multiple PDP contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word "MULTI-PLAN" instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI-PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase "C" for communication materials or an uppercase "M" for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 423.2267.

(iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

78. Section 423.2263 is added to read as follows.

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that "Other pharmacies are available in the network."

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, a Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the Part D sponsor's website about the existence of OEP.

(ii) During the OEP, a Part D sponsors may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how Part D sponsors must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA-PDs and the summary rating for PDP plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable unless using Star Ratings to convey overall Part D sponsor performance (for example, "Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the Part D sponsor must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star PDP contracts:

(i) May not market the 5-star special enrollment period, as defined in § 423.38(c)(20), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5- star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the Part D sponsor's contract received a summary rating of 2.5 stars or below in Part D for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

79. Section 423.2264 is revised to read as follows:

§ 423.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the Part D sponsor or its agents and brokers.

(a) *Unsolicited contact*. Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) Part D sponsors may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) Part D sponsors may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business*. Part D sponsors may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) A Part D sponsor may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in an MA or cost plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) Part D sponsors may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) When reaching out to a beneficiary regarding plan business, as outlined in this section, Part D sponsor must offer the beneficiary the ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries*. Part D sponsors and their agent or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, Part D sponsors and agents/brokers may not market specific Part D sponsors or benefits.

(ii) Part D sponsors holding or participating in educational events may do any of the following:

(A) Distribute communication materials.

(B) Answer beneficiary initiated questions pertaining to Part D plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) Part D sponsors holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) Part D sponsors may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 423.2260.

(i) If a marketing event directly follows an educational event, the beneficiary must be made aware of the change and given the opportunity to leave prior to the marketing event beginning.

(ii) Part D sponsors holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) Part D sponsors holding or participating in marketing events may not do any of the following:

(A) Require sign in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is "cherry-picking").

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the Part D sponsor (or the agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) Part D sponsors holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) Part D sponsors holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products such as annuities.

80. Section 423.2265 is added to read as follows:

§ 423.2265 Websites.

As required under § 423.128(d)(2), Part D sponsors must have a website.

(a) *General website requirements*. (1) Part D sponsor websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the Part D sponsor's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change

(v) Keep PDP content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) Part D sponsor websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the Part D sponsor is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the Part D sponsor.

(b) *Required content.* A Part D sponsor's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable pharmacy directory.

(4) A searchable pharmacy directory.

(5) A searchable formulary.

(6) Information on enrollees' and Part D sponsors' rights and responsibilities upon disenrollment. Part D sponsors may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the Medicare.gov electronic complaint.

(9) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(10) Prescription Drug Transition Policy.

(11) LIS Premium Summary Chart.

(12) Prescription Drug Transition Policy.

(13) A separate section or page about MTM programs providing the following:

(i) Explanation of MTM program, including eligibility requirements, the purpose and benefits of MTM, how to obtain MTM service documents including the Medication list, that the service is free, and a summary of services

(ii) Information on how to obtain information about the MTM program, including how the member will know they are eligible and enrolled into the MTM program, the comprehensive medication review and targeted medication reviews, a description of how reviews are conducted and delivered, including time commitments and materials beneficiaries will receive

(c) *Required posted materials.* A Part D sponsor's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Pharmacy Directory.

(v) Formulary.

(vi) Utilization Management Forms for physicians and enrollees.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for Physicians and Enrollees.

(ii) Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

81. Section 423.2266 is added to read as follows:

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities*. Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition in this paragraph (c) fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the "Medicare & You" handbook, or "Medicare Options Compare" (from https://www.medicare.gov) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract or participate or both.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at https://www.medicare.gov, or 1-800-MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities*. Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor. During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D plan or sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities performed on behalf of the Part D sponsor.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting*. Part D sponsor activities in the health care setting are those activities, including marketing activities that are conducted by Part D sponsor or on behalf of the Part D sponsor , or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

82. Section 423.2267 is added to read as follows:

§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content*. All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials*. Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing MA language for a Part D plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) When CMS issues standardized content, Part D sponsors--

(3) The Part D sponsor may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and Part D sponsor may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the sponsor's discretion, provided it does not conflict with the standardized content or other regulatory standards. .

(c) *Model materials*. Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, Part D sponsors:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials*. Part D sponsors must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, Part D sponsors may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which

must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content*. The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to § 423.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC)*. The EOC is a standardized communications material through which certain required information (under § 423.128(b)) must be provided annually and must be provided:

(i) To current enrollees of plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part D explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 423.128(e). Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

(3) *Annual Notice of Change (ANOC)*. The ANOC is a standardized marketing material through which plans must provide the information required under § 423.128(g)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment Checklist (PECL)*. The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form so that the enrollees understand important plan benefits and rules. The PECL references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB)*. Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on prescription drug expenses, including:

(1) Monthly plan premium

(*2*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*3*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(*4*) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) Plan sponsors may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form*. This is the model communications material through which plans must provide the information required under § 423.32(b).

(7) *Enrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.32(d).

(8) *Disenrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(9) *Formulary*. This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(10) *Low Income Subsidy (LIS) Notice*. This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(11) *Low Income Subsidy (LIS) Rider*. This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(12) *Midyear Change Notification*. This is a model communications material through which plans must provide a notice to enrollees when there is a midyear change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(13) *Non-renewal Notice*. This is a model communications material through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice in this section, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare prescription drug plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 423.507(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA-PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1-800-MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(H) Include the Part D sponsor's call center telephone number, TTY number, and hours and days of operation.

(14) *Part D Transition Letter*. This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within three days of adjudication of temporary transition fill.

(15) *Pharmacy Directory*. This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the Part D sponsor becomes aware of changes.

(A) All updates to the online pharmacy directories must be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(16) *Prescription transfer letter*. This is a model communications material that must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(17) *Star Ratings Document*. This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsors that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(18) *Coverage Determination Notices*. This is a model communications material through which plans must provide the information under § 423.568.

(19) *Excluded Provider Notices*. This is a model communications material through which plans must notify enrollees when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(20) *Notice of Denial of Medicare Prescription Drug Coverage*. This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(21) *Medicare Prescription Drug Coverage and Your Rights*. This is a standardized communications material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(22) *Medicare Part D Coverage Determination Request Form*. This is a model communications material used to collect additional information from a prescriber.

(23) *Request for Additional Information*. This is a standardized communications material used by the Part D sponsor to request a beneficiary obtain additional information from the prescriber regarding a beneficiary's exception request.

(24) *Notice of Right to an Expedited Grievance*. This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(25) *Notice of Inquiry*. This is a model communications material from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(26) *Notice of Case Status*. This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(27) *Request for Reconsideration of Medicare Prescription Drug Denial*. This is a model communications material used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(28) *Notice of Redetermination*. This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(29) *LEP Reconsideration Request Form*. This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal*. This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR)*. This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Federal Contracting Statement*. This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(33) *Star Ratings Disclaimer*. This is model content through which plans must:

(i) Convey that plan sponsors are evaluated yearly by Medicare

(ii) Convey that the ratings are based on a 5-star rating system

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(34) *Accommodations Disclaimer*. This is model content through which plans must:

(i) Convey that accommodations for persons with special needs is available

(ii) Provide a telephone number and TTY number

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events as described under § 423.2264(c).

(35) *Mailing Statements*. This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: "Important [Insert Plan Name] information."

(ii) Part D sponsors must include the following statement when mailing health and wellness information "Health and wellness or prevention information."

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(36) *Promotional Give-Away Disclaimer*. This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(37) *Provider Co-branded Material Disclaimer.* This is model content through which Part D sponsors must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned.

§ 423.2268 [Removed]

83. Section 423.2268 is removed.

84. Section 423.2274 is revised to read as follows:

§ 423.2274 Agent, broker, and other third party requirements.

If a Part D sponsor uses agents and brokers to sell its Medicare Part D plans, the requirements in paragraphs (a) through (e) of this section are applicable. If a Part D sponsor makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions*. For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent/broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. Beginning January 1, 2021, the FMV is $81. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and the Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued pursuant to § 422.312 of this chapter.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA-PD replaced with another MA or MA-PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or MA-PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA-PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA-PD plan or PDP.

(b) *Agent/broker requirements*. Agents and brokers who represent Part D sponsors must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug

plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *Part D sponsor oversight*. Part D sponsors must oversee first tier, downstream, and related entities that represent Part D sponsor to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. Part D sponsors must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the Part D sponsor has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination if required by state law.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the Part D sponsor intends to use employed, captive, or independent agents or brokers in the upcoming plan

year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, Part D sponsor may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in Part D plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements*. Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules*. (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) Part D sponsors may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) Part D sponsors may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, Part D sponsors may pay compensation at or below FMV.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors must pay pro-rated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an "unlike plan type" change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at an amount up to 50 percent of FMV.

(i) Part D sponsors may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new "like plan type".

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in a PDP, the Part D sponsor may pay only the PDP compensation (and not compensation for MA enrollment under § 422.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP enrollment.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs)*. (i) Part D sponsors must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage *(*for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation.

Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments)*. (1) Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Administrative payments can be based on enrollment provided payments are at or below the value of those services in the marketplace.

(f) *Payments for referrals*. Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries), recommendation, provision, or other means of referring beneficiaries to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA-PD plan and $25 for a referral into a PDP plan.

85. Section 423.2305 is amended by revising the definition for "Applicable discount" to read as follows.

§ 423.2305 Definitions.

* * * * *

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

86. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

87. Section 455.2 is amended by--

a. In the definition of "Credible allegation of fraud," revising paragraph (1); and

b. Adding the definition of "Fraud hotline tip" in alphabetical order.

The revision and addition read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

*Fraud hotline tip***.** A fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

88. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

89. Section 460.6 is amended by revising the definition of "Services" to read as follows:

§ 460.6 Definitions.

* * * * *

Service, as used in this part, means all services that could be required under § 460.92, including items and drugs.

* * * * *

90. Section 460.56 is added to subpart D to read as follows:

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

91. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(1) All Medicare-covered services.

(2) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

§ 460.96 [Amended]

92. Section 460.96 is amended by—

a. Removing paragraphs (a) and (b); and

b. Redesignating paragraphs (c) through (e) as paragraphs (a) through (c).

93. Section 460.98 is amended by—

a. Revising paragraph (a);

b. Adding a sentence to the end of paragraph (b)(1); and

c. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) * * *

(1) * * * These services must be furnished in accordance with § 460.70(a).

* * * * *

(4) Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

(5) The PACE organization must document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

* * * * *

94. Section 460.102 is amended by revising paragraphs (d)(1) and (d)(2)(ii) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following:

(i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.

(ii) Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(2) * * *

(ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.

(B) Participants.

(C) Caregivers.

(D) Employees.

(E) Contractors.

(F) Specialists.

(G) Designated representatives.

* * * * *

95. Section 460.104 is amended by revising paragraph (d)(2) to read as follows:

§ 460.104 Participant assessment.

* * * * *

(d) * * *

(2) *In response to a service determination request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service determination request, and may conduct reassessments as determined necessary for approved services.

* * * * *

96. Section 460.112 is amended by—

a. Adding paragraph (b)(4);

b. Redesignating paragraph (c)(3) as paragraph (c)(5); and

c. Adding new paragraphs (c)(3) and (4).

The additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

* * * * *

(b) * * *

(4) To contact 1-800-MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(c) * * *

(3) To have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

* * * * *

97. Section 460.121 is added to read as follows:

§ 460.121 Service determination process.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service determination requests in accordance with the requirements of this Part.

(b) *What is a service determination request*--(1) *Requests that constitute a service determination request.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service determination requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care.

(c) *Who can make a service determination request.* Any of the following individuals can make a service determination request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service determination request.* An individual may make a service determination request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants.

(e) *Processing a service determination request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service determination request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service determination request in full at the time the request is made, the PACE organization--

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service determination request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service determination request in accordance with paragraphs (f) through (i), (j)(2), and (*l*) of this section.

(f) *Who must review a service determination request.* The full interdisciplinary team must review and discuss each service determination request and decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team must consider all relevant information when evaluating a service determination request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in § 460.92(b).

(h) *Reassessments in response to a service determination request.* (1) If the interdisciplinary team expects to deny or partially deny a service determination request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service determination request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service determination request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*--(1) *Notice of decisions to approve a service determination request.* If the interdisciplinary team makes a determination to approve a service determination request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service determination request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service determination request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.

(iii) Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service determination request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service determination requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

98. Section 460.122 is amended by —

a. Revising the introductory text and paragraphs (b) and (c)(1), (2), and (4);

b. Redesignating paragraphs (c)(5) and (6) as paragraphs (c)(6) and (7), respectively;

c. Adding a new paragraph (c)(5);

d. Revising paragraphs (d), (g) and (h);

The revisions and additions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. A request to initiate, modify or continue a service must first be processed as a service determination request under § 460.121 before the PACE organization can process an appeal under this section.

* * * * *

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment, the PACE organization must give a participant written information on the appeals process.

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in §§ 460.121(i) and (m).

(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.

* * * * *

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

* * * * *

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

* * * * *

(g) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of partially or fully adverse decisions.* (i) Notice of any denial must--

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) At the same time the decision is made, the PACE organization must also notify the following:

(A) CMS.

(B) The State administering agency.

(h) *Actions following a favorable decision*. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

* * * * *

99. Section 460.124 is revised to read as follows:

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under §460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

100. Section 460.200 is amended by—

a. Redesignating paragraphs (b)(1) through (4) as paragraphs (b)(1)(i) through (iv), respectively;

b. Adding a new paragraph (b)(2); and

c. Revising paragraph (d).

The addition and revision read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(b) * * *

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

* * * * *

(d) *Safeguarding data and records.* A PACE organization must do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).

* * * * *

101. Section 460.210 is amended by—

a. Redesignating paragraphs (b)(4) through (12) as (b)(7) through (15); and

b. Adding new paragraphs (b)(4) through (6).

The additions read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(4) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

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Dated: October 29, 2020.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: January 6, 2021.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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